UNIVERSITY OF ALBERTA

The Development of a Malignant Wound Assessment Tool

by

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A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfillment of the requirements for the degree of Master of Public Health

Department of Public Health Sciences

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DEDICATION

I would like to dedicate this work to

my family
David, Carolyn, David and Heather Schulz

my parents
Alice and Valentine Nocent

my patients – past and present
with Malignant Wounds

ABSTRACT

The Development of a Malignant Wound Assessment Tool (MWAT)

The goal of this research was to use a valid method to develop a MWAT. The process used was descriptive survey research combining qualitative and quantitative methods employing the psychometric principles of valid instrument design. It was conducted in 2 phases, development and pilot testing, and adjusted until a point of saturation. The subjects involved were health care providers, expert judges and mentally competent patients > 18 years of age with malignant wounds. The result of this study was the MWAT.5.

The implications of creating the MWAT.5 reveal symptom themes generalizable to the population of patients with malignant wounds exists, these themes could be validly assimilated within one instrument which can be used to assess patients for clinical and research purposes. This could change the standard of practice for this patient population. Future considerations to strengthen the MWAT require field-testing to determine reliability and validity for longitudinally monitoring patients with malignant wounds.

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Dr. Robin Fainsinger Director, Division Palliative Care Medicine, University of Alberta, served as the external reviewer on the thesis committee. His opinion was greatly appreciated as he has extensive experience dealing with palliative patients.

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CHAPTER 1 - PURPOSE OF THE STUDY

Purpose and Rationale for Developing the Malignant Wound Assessment Tool (MWAT)

At the beginning of the 21st century, cancer is increasing in the aging population and patients have a greater life expectancy than they did 40 years ago. For many, cancer has become a slowly progressive, chronic disease. Patients that survive longer often develop more extensive spread of cancer, including to the skin. Malignant wounds are an exhibition of cancer progression and are likely to increase in frequency. There is a paucity of research in the literature describing the appropriate assessment and management for patients with malignant wounds (Ivetic & Lyne, 1990; Manning, 1998). As people age, and the incidence of cancer increases, it is essential to push the frontier of oncology care to strive not only for cure, but also to meet the symptom management needs of these patients.

Steensma (2000) published a striking article in the Journal of Clinical Oncology, recounting an interaction with a patient with a malignant wound. The wound was described as "a gigantic, purulent draining crater extending down nearly to her chest wall, surrounded by an eruption of necrotic, fleshy pillars and a warm, scarlet rind" (p. 3736). The patient's perspective of living with this wound was not reported. Common terminology to describe the wound was not used. This article reviews the feelings of rejection the physician incurred when the patient declined his offer for extensive surgery and emphasizes the importance of accepting the patient's autonomy in decision-making. However, one very vital step was missing – the offer of symptom management based on the patient's primary concerns.

Patients with malignant wounds have a devastating, constant reminder of cancer. Malignant wounds result from the direct invasion of cancer into the skin. They arise from primary skin tumours and cutaneous metastasis from internal malignancies such as breast or head and neck cancers. They are not uncommon, as approximately 10% of patients with metastatic internal malignancies have skin metastasis and patients have an average life expectancy of approximately 22 months after its development. Aggressive oncology efforts are often made to reduce the size or cure the cancer. Simultaneously, impeccable symptom management may reduce the physical, functional, emotional and

social distress that patients with malignant wounds experience. A thorough assessment of patients with malignant wounds is essential to identify and manage these symptoms.

Preliminary research and literature searches were conducted to determine the signs and symptoms common to patients with malignant wounds. They were identified as: (a) physical signs and symptoms (pain, odour, exudate, bleeding, edema), (b) emotional stress (anxiety, depression, embarrassment, fear, self-image changes), (c) functional compromise (general performance status, mobility, head and neck function), (d) social concerns (social isolation, interaction with family and health care providers), (e) complications (fistulas and nutritional deterioration), and (f) description of the wound (appearance, size, location, growth rate). This thorough understanding of the patient guided the development of an assessment tool for patients with malignant wounds.

The malignant wound is a unique wound, requiring assessment, management and research strategies specific to its properties. It is important to address the assessment of the malignant wound as a distinct entity.

A systematic, evidence-based assessment tool for patients with malignant wounds has not been reported in the literature. Although the concept of utilizing a valid assessment tool on patients with *benign* wounds has been well established in clinical and research practice, the benign wound assessment cannot be applied to malignant wounds. The benign wound is composed of benign granulation tissue rather than malignant tumour cells. Patients with malignant wounds differ significantly from those with benign wounds in terms of wound characteristics, growth patterns, treatment approaches, response to treatment, and the patient's response to the wound. In addition, they often have a progressive underlying malignant disease process to deal with requiring specific local or systemic therapy. Patients with malignant wounds require a unique assessment designed specifically to monitor their concerns.

The text, "Approaching Death, Improving Care at the End of Life" (Field & Cassel, 1997) delves into the philosophy of advancing care at the end of life in an exquisite fashion. These authors recommend that health care providers, policymakers, and consumer groups should "strengthen methods for measuring the quality of life and other outcomes of care for dying patients and those close to them; …[and] develop better

tools and strategies for improving the quality of life..." (p. 8). MacDonald (1995) claims impeccable symptom management is an integral component of oncology care.

The purpose of this thesis was to develop a valid process to create an organized, reproducible assessment tool specific to patients with malignant wounds. It answered the research question: Can a valid process be used to create an assessment tool for patients with malignant wounds? It was based on the premise that patients with malignant wounds can be validly assessed with an assessment tool (questionnaire / instrument). The tool development required a significant knowledge base from both the medical and psychometric literature. The process of tool development was accomplished through achieving specific objectives.

The objective of this thesis was to follow a valid process to create an assessment tool for the population of patients with malignant wounds -- the Malignant Wound Assessment Tool (MWAT). The final tool was titled the Schulz Malignant Wound Assessment Tool. It was accomplished by: (a) determining symptoms common to patients with malignant wounds, (b) identifying concerns that require evaluation in patients with malignant wounds, (c) applying psychometric principles in the development of the MWAT, (d) pilot testing the MWAT, (e) having patients and interviewers evaluate the MWAT, and (f) refining the MWAT until it was acceptable as a clinical assessment tool. The application of this valid process resulted in creating an assessment tool for patients with malignant wounds, the MWAT.5. Future research is necessary to determine the validity and reliability by longitudinally monitoring patients with malignant wounds.

The direct theoretical implications drawn from the MWAT development were numerous. Symptom themes for patients with malignant wounds were identified. The MWAT.5 was created using a valid method. It probably is valid in assessing patients with malignant wounds and is clinically useful as determined by the pilot test patients and two researchers. It was designed to be a clinically useful guide for health care providers with and without experience assessing patients with malignant wounds. The MWAT can be applied to the range of patients with malignant wounds, and the terminology for assessing patients with malignant wounds within the MWAT may be accepted as universal assessment terms. The use of the MWAT should improve communication

between health care providers. Finally, the MWAT could potentially be the outcome measure for researching patients with malignant wounds.

Ethics Approval

Ethics approval was granted at the outset of this project. The MWAT was submitted to appropriate ethics committees prior to patient entry in London, Ontario and Edmonton, Alberta. The Health Research Ethics Boards of the University of Alberta Health Sciences Faculties, the Cross Cancer Institute, and the University of Western Ontario, Canada, reviewed the protocol and found it to be acceptable within the limitations of human experimentation.

No deleterious effects were expected from the malignant wound assessment tool unless the patients do not feel comfortable with a history and physical examination. Photographs were taken as part of the MWAT to complete the physical examination of a wound. The time commitment by patients was expected to be approximately one hour. Patients were well informed that their care would not be compromised if they refused to enter or if they did not complete the MWAT.

Overview of Thesis

The MWAT was created using a valid process. It was designed to assess patients with malignant wounds. The MWAT has the potential to change the standard of practice for patients with malignant wounds. However, future field research is required to determine if the MWAT is a valid, reliable assessment tool. This research should evaluate a large number of patients in multiple settings.

This thesis consists of six chapters. This is Chapter 1, which summarizes the Purpose of the Study. Chapter 2, Literature Review, outlines the medical and psychometric evidence necessary to support the process of the MWAT development. Chapter 3, Preliminary Research, presents the study that identified the symptoms and signs common to patients with malignant wounds that were needed for content validity of the MWAT. Chapter 4, Methods, defines and outlines the psychometric principles followed to develop and pilot test the MWAT. Chapter 5, Results, states the results of the developing, pilot testing, and adjusting the MWAT. Chapter 6, Discussion and

Recommendations, defends the validity claims of the MWAT, discusses inferences drawn from its development and outlines potential future research to study the validity and reliability of the application of the final MWAT on patients with malignant wounds.

CHAPTER 2 - LITERATURE REVIEW

The Development of a Malignant Wound Assessment Tool

The MWAT instrument development required a working knowledge of medical and psychometric literature. This chapter provides a summary of the literature required to understand these two concepts.

Medical Literature Review

The medical literature reviews: (a) the use of standardized wound assessments, (b) signs and symptoms to be included in the malignant wound patient assessment, (c) definitions of the terms; malignant wound, cutaneous metastasis and extension of tumour into the skin, (d) prevalence and life expectancy of patients with cutaneous metastasis, (e) tumour origin, mechanism of spread and location of the wound, and (f) wound classification to document appearance of the wound. The search included Medline, EMBASE and Cancer lit using MeSH headings malignant, wound, cutaneous, metastasis, textbook review and discussions with experts in the field.

Standardized Wound Assessments

The purpose for developing the MWAT was to create a standardized assessment of patients with malignant wounds. The concept of using a standardized assessment of benign wounds has been demonstrated. A staging system (assessment) for pressure ulcers was established in 1989 (Bates-Jensen, 1997). Bates-Jensen (1997, p. 39) stated, "The First National Consensus Development Conference on Pressure Ulcers sponsored by the National Pressure Ulcer Advisory Panel (NPUAP) in 1989 recommended adoption of a uniform staging system to assist with communication and research in the field." Later, the Agency for Health Care Policy and Research (AHCPR) recommended it for universal use. This standardized patient evaluation has changed the assessment, management, research, and product development for patients with benign pressure ulcers over the last 10 years. Malignant wounds require a unique assessment because these wounds and their treatment are fundamentally different from benign wounds.

Signs and Symptoms to be Included in Patient Assessment

Assessing the daily concerns of patients with malignant wounds has not been a focus of medical research or practice in the past. It is not described in major oncology textbooks including Clinical Oncology (Abeloff, Armitage, Lichter, & Niederhuber, 1995), Cancer Medicine (Holland, Bast, Morton, Frei, Kute & Weichselbawn, 1997), or Cancer Principles & Practice of Oncology (Huang, 1997). However, a thorough discussion is present in the Oxford Textbook of Palliative Medicine (Miller, 1998) in both medical and nursing chapters. The nursing literature on patients with malignant wounds, both in text and journal articles, describes the symptoms and signs associated with these wounds and specifically addresses the requirements for an appropriate assessment. Most of the published information on patients with malignant wounds is comprised of case based reports (Hastings, 1993).

Grocott (1995a) discussed the development of a wound assessment tool. The article stated that, "the generation of items for the tool involved specifying the measurable symptoms and problems that are associated with the management of fungating wounds as identified in the literature and from clinical practice." (p. 333). These concerns included: (a) the presence of adherent and non-adherent necrotic tissue, (b) exudate, (c) episodes of bleeding owing to trauma from dressings, (d) pain on removal and renewal of dressings, (e) surrounding skin condition, (f) perception of odour, (g) episodes of clinical infection, (h) items associated with the impact of the wound on daily life, (i) comfort of dressings, (j) cosmetic effect, (k) numbers of dressing changes in 24 hours, (l) time taken for dressing changes, and (m) numbers of dressing reinforcements required in 24 hours. Two years later, Grocott and Dip (1997) reported the evaluation of a tool they created to evaluate the management of fungating wounds.

Based on the similarity between Grocott's goals (1995a; Grocott & Dip, 1997) for developing an assessment tool for patients with malignant wounds and the purpose of this research, it was necessary to contact this author directly. Through personal communication (approximately November, 1999) it was discovered that Grocott is developing a tool to assess the effectiveness of dressings used in the management of

patients with malignant wounds rather the direct assessment of the patient. Her tool is currently not published and is not in the public domain for use. In conclusion, Grocott's focus is different from the primary purpose of this study. The development of the MWAT was designed explicitly to assess the patient.

Haisfield-Wolfe and Baxendale-Cox (1999) stated malignant cutaneous wounds should be staged and that a staging system was feasible but needed refinement. This study enrolled 13 patients and assessed patients with digital imaging and the Hopkins Wound Assessment Tool (HWAT) a generic wound tool. They found digital imaging could document wound changes over time and the computer was an effective tool to assess malignant wounds. They staged the apparent wound depth rather than the wound classification by clinical diagnosis. This staging system documented the wound alone, and did not report the patients lived experience except for the recording of pain and odour on a dichotomous scale (yes/no).

Miller (1998) stated a comprehensive assessment for a patient with a malignant wound should include: (a) the history of the wound, how long it has been present, previous treatments and their effectiveness; (b) physical exam of the wound, diameter, depth, colour, and odour; (c) bacteria status, exudate and bleeding; (d) conditions that compromise the situation such as poor nutrition, previous radiation medication, and tumour growth; (e) pain, (f) psychological consequences of the wound including depression, altered body image, anxiety, shame, embarrassment, and isolation; and (g) the support patients receive at home. Evidence-based referencing did not accompany this list of requirements for the patient assessment.

Moody and Grocott (1993) published a nursing article outlining the assessment and management of patients with malignant wounds. They stated, "to be effective, it is essential that assessment is undertaken within a holistic approach… an integral part of holistic care is the systematic collection, assimilation, recording and utilisation of relevant patient information." (p. 589). They went on to outline the criteria for assessing patients with malignant fungating wounds. They stated the assessment should include the following concerns: (a) patient assessment – causes of the wound, record of previous and current treatment, general health status, nutritional intake, patient environment and career, socio-economic data, insight into disease, the impact of the wound on daily life

for patient and care provider, health care support being provided, and (b) wound assessment – describe the wound appearance, exudate, bleeding, fistula, infection, pain, pruritis, surrounding skin, and wound site and size.

General health status tools have been developed and are widely used in oncology care both clinically and in research. Moody and Grocott (1993) stated it would be of value to measure the general health of the individual with a malignant wound. Yates, Chalmer, and McKegney (1980) evaluated the validity and reliability of the Karnofsky Performance Status Scale (KPS) to determine its value in assessing advanced cancer patients. They concluded the KPS had a high degree of validity as a global indicator of the functional status of cancer patients (Appendix 2, p. 112).

Haisfield-Wolfe and Rund (1997) also outlined the assessment necessary for patients with malignant wounds within their protocol for the care of malignant cutaneous wounds. It included: (a) wound assessment – size and configuration, area of involvement, wound colour(s), extension of tumour with fistula formation or into the surrounding tissue, odour, bleeding, pain, pruritus, desquamation, impingement, invasion of organ systems, and (b) patient assessment – emotional impact on patient, family, impact of altered self-appearance, wound care capabilities of patient and family, financial impact, funds available for wound care products.

These articles were primarily based on anecdotal, experiential evidence and were a significant addition to the literature. However, this evidence was weak, and if the content for the MWAT were to be based solely on these reports, the validity of the process of creating the tool would have been jeopardised. Therefore, it was decided preliminary research was essential to have stronger evidence for content validity of the MWAT. The preliminary research is reported in chapter 3.

Definition of Terms for Malignant Wound

Since the malignant wound is the central concern of this entire study, it is vital that the term be understood. The terms; malignant wounds, malignant cutaneous wounds, fungating wounds, cutaneous metastases, and tumour invasion to the skin, are often mingled, or interchangeably substituted in research and the literature. Clarification of

these terms was necessary to avoid confusion throughout this research endeavor. They represent overlapping concepts, with slightly different definitions, and patient populations.

Cooper, (1993) (as cited in Haisfield-Wolfe & Rund, 1997) described a malignant wound as "a break in the epidermal integrity by infiltration of malignant cells" (p. 56). This definition has not been validated, nor debated in the literature. A break in the epidermis is not required to make a diagnosis of a benign wound. Therefore, it is reasonable to question if it must be present to make a diagnosis of a malignant wound.

Haisfield-Wolfe and Baxendale-Cox (1999) reported staging of malignant cutaneous wounds, which were defined as "primary or metastatic skin lesions of cancerous infiltration that are different in location and progression from traditionally encountered wounds" (p. 1055). There was no explanation as to the origin or evidence to support this definition. They went on to suggest a staging system where -- stage 1 -- was a closed wound with intact skin. This statement was in contrasted with Cooper's staging, (1993) (as cited in Haisfield-Wolfe & Rund, 1997), which claimed the epidermal integrity must be broken. The term malignant cutaneous wound has redundancies within it as, cutaneous, means skin, and wounds occur in the skin therefore the term of malignant wound may be preferable.

Malignant wounds are often reported as fungating wounds. Hallett (1995) stated "fungating wounds were the result of cancerous infiltration of epithelium and the surrounding blood and lymphatic vessels" (p. 81). The concern with the use of the term fungating wound is that a fungating malignant wound is a description of one class of malignant wound rather than an all-inclusive term for the population of patients with cancer spread to the skin.

Lookingbill, Spangler, and Sexton (1990) described cutaneous metastases as "lesions in the dermis or subcutaneous tissue that were noncontiguous with the primary neoplasm" (p. 19). There was no clarification as to why tumour that has spread to the epidermis (rather than just the dermis or subcutaneous tissue) was not included in this definition. Not all cutaneous metastases result in a symptomatic malignant wounds as some remain as a symptomatic subcutaneous nodules. It is not clear then, if the literature

that reports the frequency of cutaneous metastasis is representative of the population of patients with malignant wounds.

Lookingbill et al. (1990) defined cutaneous involvement by direct extension, "as a skin lesion produced by the primary tumour mass" (p. 19). Presumably, this definition implies the skin lesion and the primary tumour are confluent. It is uncertain if this includes both primary skin tumours and internal malignancies that have direct extension to the skin, such as breast cancer that has spread to the chest wall.

This discussion was relevant to this study because the term 'malignant wound' defines the patient population the MWAT applies to. Since a clear definition for the term malignant wound does not exist and one was required for this research, a broad, simply definition was used. For the purposes of this research, the term malignant wound refers to the invasion by cancer into the skin.

Frequency and Life Expectancy of Patients with Cutaneous Metastasis

In a retrospective review of the Tumour Registry at the Pennsylvania State University, Lookingbill, Spangler and Helm, (1993) reported the frequency and life expectancy of patients with cutaneous metastases. Life expectancy has increased from 3 months (Reingold, 1966 as cited in Lookingbill et al., 1993) to 1- 34 months, averaging 21.7 months. The increased life expectancy was not explained but it may have resulted from improved treatment outcome, or data collecting, or a combination of these. The frequency of cutaneous metastases was 420/4020 (10.5%) of patients with metastatic disease. This was an important report but the following questions remained unanswered: (a) What were the criteria for entry into the database? (b) Were cancer patients who did not receive oncology treatment, (those too ill, poor or those who declined treatment) entered into the cancer registry? (c) How was the database established? (d) Was the frequency of cutaneous metastases derived from primary or secondary analysis of the database? (e) Was each patient examined specifically for cutaneous metastases? Yet, this study still remains one of the best evidence-based reports in the literature to determine the frequency of cutaneous metastases. The frequency of malignant wound development from cutaneous metastases has not been reported in the literature.

Tumour Origin, Mechanism of Spread and Location of the Wound

Malignant wounds have arisen from primary skin carcinomas, cutaneous metastases from internal malignancy, and direct tumour extension to the skin from internal malignancies. Multiple tumour types have been reported to cause cutaneous metastases. Primary skin tumours, for example, squamous cell, in the head and neck region, basal cell carcinoma, melanoma and others can spread and require symptomatic management. Holland et al., (1997) reported the internal malignancies with a tendency to cutaneous metastasis were: (a) in females, breast, melanoma, ovarian, large intestine, lung, sarcoma, adenoma and oral cavity, and (b) in males, lung, large intestine, melanoma, kidney, stomach, esophagus, sarcoma and pancreas. This did not include the head and neck carcinomas presumably because they were considered direct extension of tumour rather than a metastasis. Lookingbill, et al., (1990) reported head and neck cancers collectively were second only to breast in developing cutaneous metastases.

The mechanism of dissemination (spread) of internal malignancies to the skin often dictates the location of the wound. Understanding the physiology that determines the location of the wound, promotes a greater understanding of the probable wound progression over time. Holland et al., (1997) reported dissemination primarily occurs through the lymphatic system particularity in breast and oral cavity, and probably for lung and renal cell carcinomas. Tumours with distant metastasis such as melanoma may spread hematogenously. These wounds are typically located on the chest and abdomen, followed by head and neck regions but rarely in the extremities, except in melanoma (Abeloff et al., 1995). The level of evidence to support these claims was not reported.

Malignant Wound Classification to Document the Appearance of the Wound

Documentation of the appearance of the wound is a central feature in wound assessment. A malignant wound classification system does not exist. Descriptions of malignant wounds have been reported in breast cancer (Mortimer, 1998). Descriptions of malignant wounds based on appearance of the tumour have been outlined in Table 2.1 below.

Table 2 1: Descriptions of Malignant Wounds

Malignant Wound Appearance	Wound Descriptions
Nodules and induration	Subcutaneous nodules
Subcutaneous Spread	Carcinoma erysipeloides (erythema, appearance of
- flat, spreading wound,	cellulitis)
+/- open areas	Carcinoma en cuirasse (dry, flat indurated skin)
	Elephantiasic skin changes (thick, raised, indurated skin)
	Schirrhous dermal reaction (scleraderma-like tightness)
Fungating and ulcerating	Fungating
	Ulcerating
Zosteriform lesions	Zosteriform lesions (appearance similar to herpes zoster)
Other	Wounds with mixed appearances

Four phases of subcutaneous spread of malignancy have been reported in breast cancer (Mortimer, 1998). Carcinoma erysipeloides is the initial phase of subcutaneous tumour invasion with spreading sheets of erythema and inflammation, it is light pink in colour. Carcinoma en cuirasse, is hard, dry and indurated skin and subcutaneous tissue. It may involve extensive body service areas primarily on the thorax and upper extremities. Elephantiasic skin changes are associated with dermal stasis, hyperkeratosis and papillomatosis. The tumour appears as thick, raised, indurated skin. Schirrhous dermal reaction (localized scleraderma) is the invasion of tumour into the skin causing tightening of the skin to the point of immobility. Not all patients with subcutaneous tumour progress through all four stages.

Mortimer (1998) described fungating and/or ulcerating cutaneous metastases. Fungating tumours show characteristics of both proliferation and ulceration because the proliferating mass have an inadequate blood supply which results in tumour infarcts, necrosis and sloughing allowing ulceration within the fungating mass. Fungating and ulcerating features occur simultaneously. Fungating malignant wounds occur most commonly in breast cancer, but also in lung, stomach, head and neck, uterus, kidney, ovary, colon, bladder, melanoma, and lymphoma.

Ulcerating malignant wounds were not always associated with fungating features. Head and neck tumours, bowel, lymphoma (Abeloff et al., 1995; Holland et al., 1997), squamous cell, and basal cell carcinoma (Abeloff et al., 1995) amongst others, develop ulcers without fungating features. Fistula formation may develop within an ulcerating wound. Zosteriform (Thiers, 1986) or zoster-like distribution of carcinoma resulted from perineural lymphatic spread of malignancy. Many malignant wound patients presented with features mixed from more than one descriptive category.

Malignant wound classification is not clear in the literature. This has implications in the MWAT design because it is standard practice to describe the wound during a wound assessment and wound classification would have been useful within the MWAT. Wound descriptions will be identified in the MWAT with the goal of developing a classification system in the future.

This literature search outlined the malignant wound and the concerns that require assessing. However, the organization of that assessment within a Malignant Wound Assessment Tool had not yet been determined. It was essential to investigate the psychometric literature for direction in instrument design to ensure the MWAT would be developed in a valid manner.

Psychometric Literature Review

Psychometric research is designed to investigate how psychological variables are operationalized for the purposes of measurement (Vogt, 1993). The psychometric literature supporting instrument development includes: (a) measurement selection strategies - the use of survey research to capture patients concerns and combining quantitative and qualitative research within surveys, (b) introduction to instrument

development - formatting an instrument and pilot testing new instruments, and (c) instrument validity. The method to conduct this research was obtained primarily from recent textbooks written by Crocker and Algina (1986), Osterlind (1998), Patton (1990), Shi (1997), and Streiner and Norman (1995). The journal articles supporting these textbooks were also used including: Guyatt, Feeny, and Patrick (1992); Guba and Lincoln (1994); Juniper, Guyatt, and Jaeschke (1996); Juniper, Guyatt, Streiner, and King (1997); Steckler (1989); and, Steckler, McLeroy, Goodman, Bird, and McCormick (1992).

Measurement Selection Strategies

Survey Research

Steckler (1989) noted that researchers hypothesize associations between symptoms, behaviors, and diseases faster than questionnaires/tools to measure these associations can be constructed. It is difficult to evaluate associations before valid, reliable tools are developed. The development of these tools has proven to be difficult, costly, and time-consuming scientific endeavors.

Shi (1997) supported the use of descriptive survey research to identify characteristics, feelings, attitudes, experiences, and opinions of a population and their distribution within the population. Surveys can evaluate symptoms and population demographics through a single instrument. Instruments can be an efficient data gathering technique, and that data can be reanalyzed at a later date as secondary data. Surveys allow cumulative scientific knowledge to unfold. New hypotheses to test variables have been discovered from surveys, which may be tested experimentally.

Shi also reported that survey research have weaknesses. These weaknesses include: (a) some questions seem superficial or artificial as a result of standardized format, (b) surveys cannot measure actual actions or behaviours, (c) the results rely on self-report, and the accuracy depends on the interpretations of questions, (d) patients can deliberately misrepresent facts because they tend to provide socially desirable answers particularly regarding sensitive issues, (e) the single interview survey has not been shown to permit an in-depth appreciation of the patients' real life situation and history, and (f)

circumstances present at the time of the survey strongly influence both patient perceptions and behaviours. Therefore, the validity of survey results can be weak at times.

Combining Quantitative and Qualitative Survey Research

Steckler et al, (1992) stated quantitative research method results in factual, reliable, outcome data that is often generalizeable to a wide population. It was chosen to develop unbiased measurement tools to determine associations and causal relationships between the variables being examined. This study of variables allows an outcome to be predicted. The objectivity of the study is improved by researchers deliberately creating a distance between: (a) the participant and the social phenomenon being studied, and (b) themselves. Researchers create this distance with fixed response options within survey questionnaires (respondents can not express their personal views, they must choose a response from a predetermined category).

Steckler, (1989) stated that qualitative research methods produce rich, detailed information from the participants' perspective. The qualitative perspective permits analysis of social phenomena by closely observing individuals within a population. The purpose of qualitative research is to develop an understanding of how a patient perceives living with the disease being studied.

Qualitative and quantitative methods were developed on different philosophies. Shi (1997) and Steckler (1989) both claimed qualitative and quantitative survey techniques could be combined within a single survey and that integrating these two methods is a valuable way to capture patients lived experience. Qualitative and quantitative research assumptions are different but complimentary and the limitations of each are compensated by the strength of the other as outlined in Table 2.2 below (Steckler, 1989; Steckler et al., 1992). This concept strongly supports the interdisciplinary methodology approach of combining quantitative and qualitative methods within a single survey.

Table 2 2: Attributes of Quantitative and Qualitative Evaluation Methods

Quantitative	Qualitative
Deductive	Inductive
- Verification and outcome oriented	- Discovery and process oriented
Measurement tends to be objective	Measurement tends to be subjective
Reliable	Valid
- Technology as the instrument (the evaluator is removed from the data)	- The evaluator as the instrument (the evaluator is close to the data)
Generalizable	Ungeneralizable
- The outsider's perspective	- The insider's perspective
- Population oriented	- Case oriented

Steckler (1989) stated the primary weakness of combining qualitative and quantitative methods within one survey is that both research methods tend to be used in their most basic forms. In depth ethnographic technology and advanced quantitative testing of complex hypotheses have not typically been combined. A team of each paradigm researching the same question would be required to elevate the level of sophistication of each of the qualitative and quantitative components within the tool. Assessing patients with malignant wounds requires both the subjective evaluation of the patients lived experience and the objective examination of the wound. The combination of qualitative and quantitative approaches has strengthened this instrument design.

Introduction to Instrument Development

The first step in instrument development was to review and select the most theoretically appropriate instrument design based on the outcome desired. Juniper et al., (1996) reviewed possible instrument designs. An evaluative instrument is designed to: (a) identify potentially important patient concerns, (b) select the most important concerns/items, (c) present the selected test items to allow response gradients that report within-patient change, and (d) detect small patient change over time. The MWAT was developed as an evaluative instrument because the primary outcomes are to measure: (a) patient concerns by gradients, and (b) within-patient change over time (even though the

validity of 'change over time' will be tested in a future research design). Guyatt et al., (1993) support the use of evaluative instruments to measure health.

Instrument development for the evaluative tool is divided into five phases: (a) specifying measurement goals, (b) item generation, (c) item reduction, (d) questionnaire formatting, and (e) validity of instrument development. This process is outlined in Table 2.3 (Appendix 1, p. 93). This table was created by amalgamating references by Crocker and Algina (1986) and Juniper et al., (1996) to ensure the most appropriate instrument design for the MWAT development. The phases of instrument development in Table 2.3 from; specifying measurement goals, to, patient and interviewer evaluation of the instrument, are thoroughly explained and implemented in Chapter 4 - Methods. Only an outline of these principles is provided here (see Appendix 1, p. 93) for details.

Instrument Validity

Validity

The concept of validity is the principle concern in developing instruments. It has been defined within the AERA/APA/NCME Standards, 1985 (as cited in Osterlind, 1998):

> *Validity is the most important consideration in test development. The concept refers to the appropriateness, meaningfulness, and usefulness of the specific inferences made from test scores. Test validation is a process of accumulating evidence to support such inferences. A variety of inferences may be made from scores produced by a given test, and there are many ways of accumulating evidence to support any particular inference. Validity, however, is a unitary concept. Although evidence may be accumulated in many ways, validity always refers to the degree to which that evidence supports the inferences that are made from the scores. The inferences regarding specific uses of a test are validated, not the test itself (p. 9).*

Osterlind (1998) clearly defines the concept of validity. The concept of validity states that *test inferences* rather than *direct measurements* are vital for validity claims. It is the interpretation of the test scores through inferences that is validated, not the test itself. The evidence that defends the interpretation of the test results is the evidence to support validity claims of the instrument. Validity of a test is not a concrete

phenomenon. Rather, validity is a process of gathering evidence. There are many methods of gathering evidence to support validity of an inference (as outlined below). The gathered evidence dictates the type of inferences that are appropriately made. Each inference must be supported with evidence.

Validity is reported in degrees. A high degree of validity for an inference is supported with a large amount of evidence while a low degree of validity for an inference is weakly supported with a small amount of evidence. The definition of validity states that validity the facets of validity have come together as a unitary concept, blending content, criterion and construct validity. The evaluation of a new instrument / tool must include whether the instrument is measuring what it set out to measure – its validity.

Measuring Validity

The validity of a research endeavor is strengthened through triangulation of information. Triangulation is the combination of results of several research methods, qualitative and quantitative, when studying one topic (Patton, 1990). This occurs by including multiple data sources, opinions of several evaluators and the use of multiple perspectives to interpret a single set of data (multiple theories) (Shi, 1997). This is a process of cross-validation of information. Triangulation strengthens the inferences drawn from the research.

Ebel stated that precise item construction is in itself evidence for instrument validity (as cited in Osterlind, 1998). A valid tool follows a defined set of assumptions to meet the criteria for good test items development. There are seven essential criteria to support validity claims of a test item development and three conditions for test development. Reliability of the instrument development becomes inherent features within validity.

The criteria Osterlind (1998) outlines as essential for validity are as follows:

1. Demonstrate congruence criterion, which is the degree of similarity between each item and its test item specifications. This is accomplished by ensuring items are generated by matching the defined objectives within the test and test item specifications.

2. Write each objective clearly to identify the item pool.
3. Use methods to reduce systematic measurement error, to reduce bias. Reduce the chance of over or under-estimating the population parameter by counting the number of items representing each specification.
4. Design the format to be suitable to the test goals.
5. Design each item to meet specific technical assumptions. These assumptions include unidimensionality of items and local independence of the items.
    a. The assumption of unidimensionality states a specific response results from a single pre-determined construct. It can never be completely satisfied because there are too many unknown and uncontrollable factors that can affect the respondent's answer. It is important however to aim for this goal.
    b. The concept of local independence states that the responses of each item are not dependent on the responses to other items.
6. The items need to be in a uniform editorial style. They need to be reviewed for spelling, grammar, punctuation and word usage.
7. The items must meet legal and ethical standards. The instrument must have appropriate ethics approval prior to administration. The items cannot be taken from a copyrighted source.

Overall instrument development contributes to validity by meeting the following conditions.

1. The purpose of the instrument must be well defined, which includes a precise description of the test's content.
2. The instrument's purpose and content needs to be outlined in a set of specifications.
3. Demonstrate the congruence between test items and their defined specifications in an organized method.

The criteria for validity are mentioned three times in this research. They are: (a) introduced here, (b) incorporated into methodology, in Chapter 4 - Methods, to ensure

validity of the development of the MWAT, and (c) the degree of validity for each criteria is reviewed in the Chapter 6 - Discussions and Recommendations.

Summary

The paucity and vagueness of the literature regarding malignant wounds emphasizes the extreme need to conduct evidence-based research for this population of desperate patients that watch their cancer grow across their body.

The review of the medical literature assisted in directing this research endeavour. It outlined: (a) standardized assessments have been developed and accepted universally to assess benign wounds, (b) signs and symptoms for patients with malignant wounds that require assessment were based on case-based information, (c) the term malignant wound was not clearly defined and needs further clarification in the future, for the purposes of this research endeavor, the term malignant wound simply meant; the invasion by cancer into the skin, (d) the frequency and life expectancy of patients with malignant wounds has increased over the past 30 years, in the early 1990's it was reported that 10.5% of patients with metastatic cancer have malignant wounds and live an average of 21.7 months, (e) malignant wounds most commonly arise from breast, head and neck and lung cancers, (f) they typically spread through the lymphatic system and therefore are located close to the primary tumour, (g) they are most commonly located on the chest and abdomen, then head and neck regions and rarely on the extremities, and (h) a valid malignant wound classification system was not found in the literature, but descriptions of malignant wounds were found particularly for breast cancer. A valid reproducible assessment requires strict application of psychometric principles of instrument design.

The psychometric principles appropriate for health related tool development were reviewed. Survey research has been shown to identify characteristics, feelings, attitudes, experiences, and opinions of a population and their distribution within the population. Although, surveys may be superficial and rely on self report. The combination of quantitative and qualitative research methods strengthens the survey design. This allows examination of factual, reliable, outcome data that is often generalizeable to a wide population simultaneously with an evaluation of how a patient perceives living with the

disease being studied. Unfortunately, elementary levels of qualitative and quantitative research techniques are typically used within an instrument.

Evaluative instruments are often used in health-related surveys. This technique is designed to ensure the patient specific concerns are evaluated, and when it is used to longitudinally monitor patients over time, it should be responsive to patient changes. It is necessary to follow strict criteria to claim the tool development was conducted in a valid manner.

Based on this literature, it is reasonable to believe that devising a systematic survey to approach patients with malignant wounds is appropriate. It then became important to apply psychometric principles to develop the malignant wound assessment tool. These principles become the essence of the research methodology.

Since the signs and symptoms that require assessment within the MWAT were based on case-based information, this evidence was determined to be too weak to support the validity of the MWAT content. Preliminary research was conducted, Chapter 3, to strengthen the content validity of the tool.

CHAPTER 3 - PRELIMINARY RESEARCH

Introduction

Patients with malignant wounds have multiple symptoms and signs relating directly to the wound and the human response to living with the wound. Health care providers have not yet researched this symptom complex. Case-based reports state these patients have concerns that recur in symptom themes. This literature is a valuable resource but scientifically too soft to confidently determine the symptoms and signs common to patients with malignant wounds.

The purpose of this preliminary research was to identify this constellation of symptoms with some degree of certainty to incorporate the results into the MWAT development. Juniper et al. (1996) suggests over 100 patient experiences are theoretically necessary to conclude the symptom complex with confidence. Patients with malignant wounds are generally unwell with metastatic cancer and are located in a broad geographical distribution. Patient concerns, as reported by experienced health care providers, were collected and analyzed to identify the constellation of symptoms common to patients with malignant wounds in this project. Health care providers were requested to complete an open-ended qualitative survey, asking them to recount and record the symptoms from one of their patients (Appendix 3, p. 114).

The results of this study promise to strengthen the case-based literature reported by Schulz (1999), Haisfield-Wolfe and Rund (1997), and Moody and Grocott (1993). These reports discuss patient symptoms and their relationship with wound management. The concerns identified in the literature include; drainage, odour, pain, bleeding, wound dressings, emotional and social stress, and difficulty performing normal daily activities. This research was designed to support, or refute these reports for the purposes of establishing content validity of the MWAT. The research question posed was: can the signs and symptoms common to patients with malignant wounds be identified? The signs and symptoms identified in the results of this survey were used directly in the content of the MWAT.

Method

The purpose of this section is to explain research design, description of the target population, sampling strategy, and data collection strategies for the preliminary research.

Research Design

An open-ended qualitative survey (Appendix 3, p. 114) was completed at malignant wound workshops. Due to the quasi-experimental nature of this study, randomization was not an option. The intent and timeframe of the study did not permit the time needed to validate and calculate a reliability index.

Description of the Target Population

Experienced health care providers, primarily nurses, were surveyed as patient representatives. One hundred and thirty-six health care workers enrolled in malignant wounds workshops completed surveys from September to December, 1999 in Edmonton, Alberta, Winnipeg, Manitoba, and Toronto, London, and Windsor, Ontario. All care providers who responded to the survey had experience in managing patients with malignant wounds.

Sampling Strategy

Participants were a convenience sample drawn from malignant wound workshops as described above. Non-probability purposeful sampling of self-selected care providers' was carried out. This method was based on expert judgment of the principle investigator. Health care providers with direct experience in managing patients with malignant wounds, the participants, were believed to be capable of reporting the symptoms their patients experienced.

The sample size of participants was determined to be approximately 100 subjects. This number has been suggested based on a level of confidence that the sign or symptom is actually of value. If patients or their representative care providers identify the presence of a symptom in proportions, the widest confidence interval around a proportion occurs

when the symptom is identified in 50% of the population. Narrower confidence intervals occur with any other proportional value. The sample size of participants used to determine content of the MWAT, can be determined based on the: (a) assumption that all symptoms occur 50% of the time, and (b) confidence interval desired (0.4 - 0.6). As the sample size increases the confidence interval reduces. A sample size of 100 participants would state that a symptom which occurs in 50% of the entire population within the confidence interval of 0.4 - 0.6. That is, the sample population would state the symptom occurs 40% to 60% of the time. This information guided the number of individual opinions required to determine the appropriate content within the MWAT.

Data Collection Strategies

The survey was designed to elicit responses using short answer format focusing on the caregivers' perspectives. The survey was conducted at the beginning of the workshop to encourage original thinking and reporting of patient symptoms. It consisted of one open-ended question asking care providers to recall, recount, and record the symptoms of one patient with a malignant wound.

Small groups of caregivers were formed and each experienced care provider discussed a patient with the group. The comments were recorded and given to the researcher. Open-ended question responses were entered into a spreadsheet using Microsoft EXCEL 1995, grouped into themes, and then coded according to recurring symptoms. Frequencies of the symptoms were tabulated and descriptive statistics were used to analyze the data.

Results

A total of 814 symptoms were reported from the 136 participants of the workshops. Each participant reported the symptoms of one patient. The unit of analysis used in this study was each reported symptom. The mean number of symptoms recorded for each patient was six (CI 95% 5.6 - 6.37). Analysis of the descriptive statistics revealed themes of signs and symptoms prevalent within this patient group.

The results from the survey were grouped into the following main themes; physical signs and symptoms (including pain, odour, exudate, bleeding and edema),

emotional stresses, social concerns, functional compromise and complications as shown in Table 3.1 below.

Table 3 1: Prevalent Symptoms of Patients with Malignant Wounds

Symptom	% of 816 Symptoms Reported
Pain	21%
Emotional Stress	18%
Odour	16%
Exudate	11%
Bleeding	10%
Functional compromise	7%
Social concerns	6%
Edema	5%
Complications	6%

The care providers' descriptions of their patient's symptoms were not restricted to a specific vocabulary. This broad vocabulary was dealt with by grouping a variety of descriptors together for each symptom theme. Table 3.2 (Appendix 1, p. 94) outlines the theme descriptors identified from the survey responses.

Each theme contains numerous symptoms. Other concerns were mentioned such as wound dressings and demographic information on this patient population that did not fall within symptom themes.

The health care providers often articulately described their patients' concerns. It is valuable to understand their comments in context with the patient scenarios. In the following passage, words written in italics are words and phrases obtained directly from the collected data.

Physical symptoms of pain, odour, exudate and bleeding were the most commonly reported symptoms. Pain or variations of pain was the single most frequently reported symptom. Descriptors on pain intensity were *"severe, discomfort, irritation, pressure,"* and *"pressure and tightness around chest"*. The quality of the pain sensation was described as *"burning, stabbing, muscle pain, heat sensitive, sensation of crawling things on skin, tactile sensitivity – unable to wear undergarments"* and *"itch"* or

"itchiness". The timing of the occurrence of pain was reported by some as pain *"with dressing changes, with wound care"* and *"with movement"*. Problems associated with the pain were stated to be *"pain with lymphoedema"* and *"pain with dressings"*. The concept of 'total pain' was mentioned as *"total physical and emotional pain"*.

Emotional stresses, collectively, were the second most frequent reported symptoms of patients living with the malignant wound. Comments within this symptom complex were related to depression, where reports of *"discouragement - a new one every day, depression, depression related to disfigurement, disruption of physical integrity, loss of dignity and despair"*. Fear of the presence of the cutaneous malignancy was reported as *"fear of"* all of the following concerns: *"dehiscence, bleeding, bleeding to death, total replacement of all by cancer, now can visualize the tumor"*, and *"visual fear"*. Patients often find it overwhelming to watch the tumor grow relentlessly. Reports of altered self-image were common including *"decreased, negative self image, loss of self image and poor self image"*. Concerns of *"disfigurement, cosmetic/esthetic distress"* in having the wound were reported as *"patient refuses to look at it, grief over rapid progression of disease"* and *"alteration in body image"*. Expressions of feeling *"dirty, creepy, 'rotting', ugly"* were reported. One report summarized these feelings as *"eating away at humanity"*. *"Physical appearance"* and *"cosmesis"* (cosmetically acceptable appearance) were considered important. The wound was *"constant reminder of cancer growth"*. Some patients were *"unable to look at [the] wound"* and had *"visual distress"* and *"emotional distress with visibility of wound"*. *"Decreases self esteem"* and *"loss of dignity"* were also reported. Other emotional reactions to living with the malignant wound were reported as *"anxiety, anger, embarrassment - patient sensitive – size of arm, denial - patients family more aware than patient, frustration, existential distress"* and *"coping issues"* were reported.

Odour was the third most common theme reported. Odour was considered within the physical sign and symptom theme. Words used to report this symptom were *"odour"* and *"smell"*. The intensity of the odour was expressed as *"dizziness and fainting due to odour, pungent, malodorous"*, and *"foul smelling drainage"*. The cause of the odour was *"odour due to sloughing nodules"* and *"infection"*. Infection was also reported as *"heat, fever, chills, odour, bleeding, exudate, erythema"* and *"maggots"*.

Other physical signs and symptoms were exudate, bleeding and edema. Exudate was reported as *"weeping, discharge, drainage"* and *"oozing"*. The quantity of exudate ranged from *"dry"* to *"copious"*. The quality of the exudate was stated to be *"serous, serosanguinous, yellow purulent"* and *"corrosiveness"*. Bleeding was another problematic physical symptom. When the responses were analyzed, two concerns were noted. First, patient characteristics including *"vascular, hemorrhage – carotid artery, anemia, spontaneous bleeding, coagulopathy, friable tumor"* were mentioned. Secondly, iatrogenic causes of bleeding were *"bleeding with dressing changes and anticoagulation"*. Edema was also a problem with comments such as, *"swollen arm, swollen leg, edema legs, arms, lymphoedema"* and *"sensitive to size of arm"* describing this symptom.

Patients' inability to function properly was reported repeatedly. These symptoms were grouped together under the theme entitled functional compromise. This included difficulty with mobility and other activities of daily living. Mobility issues were reported frequently. Expressions of *"difficulty moving, restriction in movement, decreased ability to ambulate, loss of mobility, fusing of arms, decreased range of motion, decreased mobility arm and shoulder, immobility, impaired motor function, hardening – stiffness to effect joints, difficulty with activity, immobility of extremities – due to - size of mass and drainage"* were found. *"Isolation with decreased mobility"* was noted. Inability to carry out activities of daily living normally involving the head and neck region were reported as problems with *"talking, eating, bulk of tumor on face interferes with eating, drinking, swallowing, speech compromised, drooling, blindness, invaded eyelids, retrobulbar growth, tumor growth interferes with vision, deafness"* and *"facial palsy"*.

Complicating factors were grouped together as another symptom theme. They were expressed as *"fistula drainage (stool, urine, oral secretions), gangrenous – foul copious exudate, corrosive exudate"* and *"sinus draining over the abdomen area"*. Serious issues with incontinence and discharge were reported as *"incontinence of stool, urine, vaginal discharge, rectal discharge, very difficult to keep clean, desensitization of rectal area, incontinent almost continually"* and *"stool oozing"*. Fatigue, *"physical"* and *"mental fatigue"*, as well as *"weakness"*, were reported. Comments on *"shortness of breath"* revealed problems with breathing. Nutritional concerns were commented on

periodically. Reports of patients with *hunger pangs – a wanting to 'taste' not swallow certain foods, anorexia, decreased appetite due to odour, lack of appetite* and *cachexia / anorexia* were present. It was not clear if the anorexia was related to advanced cancer progression, or directly to the malignant wound.

Social issues were commonly reported in terms of both social isolation and lack of patient independence. These issues were expressed as "*isolation – withdrawal from family and friends, social isolation, loneliness, sense of isolation with private room because of odour, shunned*" and "*confinement*". "*Acceptance in society*" was believed to be important and reports of "*feeling rejected, decreased sexuality*" and "*social pain*" support that claim. A change in the intimacy once shared with significant others were expressed as "*decreased intimate contact*". Patient independence concerns were reported as a decreased "*ability to care for self, loss of independent care, total dependency on others to meet her needs due to the debilitating process of her illness, need to depend on mother as a caregiver*" and "*caregiver stresses*". This concern was amplified by the comment "*effect on health care provider was dramatic*". Others simply reported provision of wound care was strained with an "*effect on family, visitors, caregivers, impatience of some nurses due to time to change dressing, emotional distress related to time nurses had to spend doing dressings*" and the "*effect on caregiver*". The "*appearance of wound for the caregivers sake*" was expressed as an "*embarrassment – with nurses, personally, odour being offensive to others*" and as "*embarrassment to patients self image*". Others reported a noticeable "*loss in their ability to care for others*".

Comments were made regarding issues that were not specifically patient signs or symptoms. Yet they were valid concerns on the appearance, location and rate of tumor growth. The appearance of the patients' tumor "*were ulcerating – sloughing of tumor leaving gap, fungating (cauliflower), nodular, heaviness of tissue – especially breast*". Reports of the wound being located on the "*face, chest, back, extremities* " and "*all over body*" were found. Descriptions of the rate of tumor spread were "*slow progressive, rapid, cascading, tunneling*" and "*erupting other areas*".

The skin surrounding malignant wounds can be a significant source of problems. Challenges pertaining to the skin surrounding the wound were reported as "*peri-wound*

skin [problems], poor healing from radiation therapy, surrounding skin irritation, skin breakdown, hardening of skin" and *"skin texture – felt like bubble pack"*. Effective and available wound dressings are a primary concern to patients and health care providers. Although dressing concerns were not specifically addressed, it is not surprising that many comments were made regarding the *"difficulty of bandaging"* the wounds. Issues such as the wound *"location* [causing] *difficulty"* [in] *"dressing"* and the fact that it is *"very difficult to keep clean"* were clear messages. Symptoms related to dressing changes including *"pain, bleeding, odour, containment of exudate"* and *"worry - about how to dress the wound"* were reported. Participants recorded additional concerns that were not considered patient symptoms but dealt with the care of the malignant wound.

Discussion

The constellations of symptoms and signs (referred to as the symptom themes) for patients with malignant wounds identified in this study are: physical symptoms, emotional stress, functional compromise, social concerns, and complications. Malignant wounds and the patient symptoms typically progress relentlessly. Individual patients generally experience some but not all symptoms from within the typical symptom complex identified here.

Physical symptoms included pain, odour, exudate, bleeding and edema. Collectively, these physical symptoms were the most commonly reported theme. Reports of difficulty with the severity of the symptom and coping with the presence of the symptoms were abundant.

Emotional stresses were a significant concern as the second most reported symptom theme. They dealt with personal issues such as discouragement, depression, altered self-image, fear, anxiety, anger and frustration. These reports emphasize it is onerous to cope with the process of relentless, overt progression of cancer.

Social concerns were frequently reported. These concerns involved patient interaction with others in their family and with people in society, including health care providers. The results revealed patients often become dependent on others for care because the wound is too complex to manage independently. Unfortunately, the very

individuals that the patients were required to depend on found dealing with the wound offensive at times.

Functional compromises, especially serious compromises in activities of daily living, were frequently expressed. Significant limitations in mobility, as well as eating, drinking, seeing, hearing, and tasting were all too often reported. The formation of fistulas and the presence of incontinence created unique challenges.

Patient demographics, and wound dressings were two other important topics mentioned outside the classification of patient symptoms. These concerns are equally important as patient symptoms. However, they were not the focus of this study. References were made to demographic information including tumor types, gender, age, location, and classification of the wound. Difficulty dressing the wounds was mentioned repeatedly in this survey. Appropriate dressings are a fundamental, core issue in the management of symptomatic wounds. Since this research was not designed to evaluate the concerns of dressing the wound, no further analysis or interpretation of dressings was conducted. See Grocott's (1995b) discussion of this issue.

Conclusion

The signs and symptoms common to patients with malignant wounds has been identified through analyzing results of a qualitative survey completed by experienced health care providers. This research successfully answered the research question posed: can signs and symptoms common to patients with malignant wounds be identified? The constellation of symptoms for patients with malignant wounds identified in this study was physical signs and symptoms (pain, odour, exudate, bleeding and edema), emotional stress, functional compromise, social concerns, complications (i.e., fistulas and nutritional deterioration). Patients with malignant wounds have an average of six symptoms each, as reported by the health care provider.

Health care providers with primary experience in managing patients with malignant wounds are capable of reporting patient symptoms. It is believed that health care providers have difficulty reporting the intensity or impact of symptoms on a patient's life. This study presented only symptoms patients reported to their health care

providers. Obtaining the patient perspective of the intensity and impact of the symptoms on their lives would be an extremely valuable compliment to this work.

The results of this survey add significantly to the literature for patients with malignant wounds. It contributes to the evidence-based knowledge providing a more in depth understanding of their concerns. This information provides the theoretical basis to develop a systematic approach to the assessment and management of patients with malignant wounds. The results of this exploratory research provide an acceptable groundwork for the content within the development of the Malignant Wound Assessment Tool. Chapter 4 - Methods, outlines the process used to incorporate this information into the MWAT.

CHAPTER 4 - METHODS OF THE MWAT DEVELOPMENT

The development of the MWAT as an evaluative tool clearly follows standardized guidelines of measurement in evaluative instrument development and testing. The method of this study was divided into two phases: (a) instrument development - the development of the MWAT, and (b) instrument testing - pilot testing the MWAT.

The MWAT development was carried out in the five phases: (a) specifying measurement goals, (b) item generation, (c) item reduction, (d) questionnaire (tool) formatting, and (e) validity of the tool development (Table 2.3, Appendix 1, p. 93). MWAT testing was conducted through: (a) pilot testing, and (b) patient and interviewer evaluation of the instrument.

The MWAT.1, was developed from phases a and b; MWAT.2 was the result of phases b and c; and MWAT.3 was the result of phases c, d and e. MWAT.3 was the first tool presented to patients during the pilot testing. Pilot testing the MWAT was conducted on patients with malignant wounds in two phases: (a) the MWAT was administered to patients, and (b) the patients and interviewers evaluated the MWAT.

During the pilot test, the tool was adjusted by: (a) altering the format to produce the final MWAT, (b) adding and deleting items, and (c) changing awkward items. There was a series of three MWAT's used in the pilot testing: (a) MWAT.3 was evaluated by ten patients and the researcher, which lead to the development of MWAT.4, (b) MWAT.4 was not a functional improvement and required major revisions, and (c) the MWAT.5 was a substantial improvement over MWAT.4.

The MWAT.5 was used until it was obvious significant changes were no longer required. This approach was based on published development theory (Crocker & Algina, 1986; Juniper et al., 1996). The 5 versions of the MWAT are displayed in the Appendices: Appendix 4 - MWAT.1, p. 116, Appendix 5, - MWAT.2, p. 130, Appendix 6 - MWAT.3, p. 145, Appendix 7 - MWAT.4, p. 152, and Appendix 8 - MWAT.5, p. 159.

Chapter 4 - Methods, describes: (a) participants, (b) sampling strategies, (c) data collection strategies, and (d) method of analysis for each of the MWAT development and pilot testing phases. It outlines the phases of instrument development and testing to the

point of evaluating the pilot test. The study was not designed to test the remaining phases of instrument testing outlined in Table 2.3 (Appendix 1, p. 93): (a) responsiveness, ability to detect small within-patient change over time, (b) longitudinal construct validity, and (c) interpretability of the results of the use of the tool.

Instrument Development - The Development the MWAT

Research Design

The MWAT was developed in a step-wise fashion, following psychometric principles of questionnaire design (Table 2.3, Appendix 1, p. 93). It was designed specifically to answer the research question: Can a valid process be used to create an assessment tool for patients with malignant wounds? The objective of this pilot study was to design, develop, and pilot test the MWAT.

Specifying Measurement Goals

Measurement goals were specified in attempt to achieve the desired measurement outcome. The following criteria were considered in specifying the measurement goals: primary purpose, the target population, the format, method of administration, and the approximate length of the tool. (Juniper et al., 1996). Once these criteria were defined, the theoretical instrument design was chosen.

This overview of the specified measurement goals provides a summary of the methods in developing and pilot testing the MWAT. The MWAT was primarily a disease specific, evaluative instrument. It was designed to record the current status of cancer patients with malignant wounds over the age of 18. Patients incapable of determining their own health care decisions were excluded from the study.

Ease of administration was essential for clinical and research purposes. Physical, emotional, social, and functional status measurements were completed to adequately assess these patients. It was completed in person during one-to-one interviews. It was not designed for telephone interviewing. The MWAT contains approximately 60 items and takes approximately 1 hour to administer. The order of the items within the MWAT has been designed to emulate the clinician-patient interaction. The order is the: (a)

demographic information (to gather background patient information), (b) history, and (c) physical examination.

Specifying the measurement goals directed the type of instrument to design. The MWAT was theoretically based on standardized guidelines for measurement in evaluative instrument development and testing. It was constructed to be a specific instrument to evaluate patients with malignant wounds. As with most evaluative instruments, the physical, emotional, and social issues causing patient dysfunction that occurs as a result of the disease were included in the tool.

Item Generation

Item generation was carried out to create an all-inclusive pool of potential items for the final MWAT. Items are the questions or statements within the instrument that require responses. The generation of these items was accomplished through discussions with experienced health care professionals, literature review, and preliminary research. Instruments are frequently translated into other languages and cultures, so jargon and metaphors were avoided.

The purposes of item generation in the MWAT development were to: (a) identify the content in the MWAT, (b) outline the content specification and test item specifications, and (c) determine the use of the identified content within the test items/questions in the MWAT.

Identify the Content of the MWAT

The potential content of the MWAT was identified through: (a) personal experiences while providing health care for patients with malignant wounds, (b) literature review as outlined in Chapter 2, (c) preliminary work as described in Chapter 3, and (d) discussions with expert health care providers.

Content Specifications and Test Item Specifications

The Test Content Specifications Table and the Test Item Specifications (Osterlind, 1998) were created to specify the method of utilizing the identified content within the MWAT (Tables 4.1 - 4.7, Appendix 1, pp. 98 - 103). Test item specifications identified primary domains of interest in the tool. Domains are developed from the objectives of the test. Content analysis is a data analysis approach from qualitative research (Guba & Lincoln, 1994; Patton, 1990). The method of analysis to determine the domains was content analysis. The data collected from all sources was reviewed and themes embedded in the data were extracted. The test item specifications made sure the domains were distributed proportionately, relative to the frequency of symptom occurrence to ensure the appropriate weight of importance for each topic. They also identified the relative importance between: (a) each of the domains within the MWAT, and (b) the components within each domain.

The Test Content Specifications divided the content into six domains (Table 4.1, Appendix 1, p. 97): (a) descriptive information, (b) subjective evaluation of the physical symptoms, (c) subjective evaluation of emotional issues, (d) subjective evaluation of social concerns, (e) objective evaluation of the physical examination of the wound and, (f) procedures to examine the wound. Subordinate groups defined the content of each of these domains (Table 4.1, Appendix 1, p. 97). Once the Test Content Specifications outlined the domains (major groups) and subordinate groups, the identified information was incorporated into the Test Item Specifications (Tables 4.2 - 4.7, Appendix 1, pp. 98-103) to create test items. Test Item Specifications Tables were completed for each domain (Tables 4.2 - 4.7, Appendix 1, pp. 98 - 103) as the organized method to clearly connect the selected content with the completed MWAT. The three main considerations in creating test item specifications tables included: (a) the item content, (b) the cognitive task being demanded of the respondent when replying to a test item, and (c) determining the type of item to fulfill the identified requirements desired at the time of the patient assessment, the response option (i.e., fill in the blank for patient specific information versus a rating scale to measure the intensity of a common symptom).

Creating Test Items from the Identified Content

The desired MWAT content was originally displayed in the MWAT.1 for ease of viewing and to determine a method to transform it into test items. Some of the content could be directly transferred into test items, such as the patient demographic items. However, it was significantly more difficult to transfer patient concerns directly into MWAT test items from MWAT.1 because of their complexity. A table expanding the identified concerns was created (Table 4.8, Appendix 1, p. 104). This table names the concerns and their cause and provides a description to clarify the concern. This was done to decide exactly what needed to be tested about each concern. MWAT.1 and Table 4.8 (Appendix 1, p. 104) were amalgamated to create the Test Item Specification Tables (Tables 4.2 – 4.7, Appendix 1, pp. 98 - 103). Items for the MWAT.2 were developed from the Test Item Specification Tables (Tables 4.2 - 4.7, Appendix 1, pp. 98 - 103).

A high degree of similarity between each item in MWAT.2 and the test item specifications was considered essential to satisfy the congruence criterion. The congruence criterion was accomplished by ensuring items are generated by matching the defined objectives within the test and test item specifications. The results of the all-inclusive item generation list were compiled into the MWAT.2. The MWAT.2 was a significant step in the MWAT development as it represented the first version to be externally evaluated and all other forms of the MWAT were derived from this version. This version was too comprehensive and lengthy to be used in the clinical setting so it was changed through the process of item reduction.

Item Reduction

Item reduction was the process used to reduce the all-inclusive MWAT.2 into a feasible instrument (tool), the MWAT.3. This was carried out to: (a) create the MWAT.3 for ease of administration in the clinical setting, and (b) reduce the measurement error.

Methods were used to remain patient focused and limit systematic measurement error, to reduce bias. The methods were to: (a) review the results of the preliminary

research in Chapter 3 to identify the highest frequency items (Table 3.1, p. 26), (b) conduct e-mail communication and discussions with the expert judges, (c) ensure the item specifications were met (Tables 4.2 - 4.7, Appendix 1, pp. 98 - 103), (d) review the item response options chosen for each item (Table 4.1, Appendix 1, p. 97), (e) include the causes of the patient signs or symptoms, particularly in the physical examination (Table 4.8, Appendix 1, p. 104), and (f) count the number of items representing each specification to decrease the chance of over or under-estimating the population parameter. The number of items that remained in the instrument was determined on the basis of their frequency and importance to the patient population of interest to reduce measurement error.

The MWAT.3 was designed to accommodate individual patients concerns by including open-ended, qualitative test items. Evaluative tools often identify 3 - 5 personal concerns that are unique and frequently bothersome to the individual (Abeloff et al., 1995; Juniper et al., 1996). The next step, in the process of converting MWAT.2 to MWAT.3 was to format the MWAT.3 to create a feasible tool.

Instrument (Tool) Formatting Including Response Options

The format of the MWAT refers to the order of the items and the appearance of the tool. It was necessary to consider the organizational framework, the font, font size, white space, number of items, pages, and response options. The format of the instrument was considered the interface between the researchers ideas and the patient population. The method of administration of the MWAT was considered while formatting as it determines the way in which the test items are worded and the duration of time required to complete the tool.

The format was designed to suit the purpose of the MWAT. Response options, (the types of questions asked) were matched for each test item. Formatting changes were the most significant difference between MWAT.2 and MWAT.3. These changes were driven by the expert judges' evaluations of the MWAT.2. There were five types of response options within the MWAT.3: (a) continuous interval rating scales, (b)

categorical, dichotomous scales, (c) quantitative, fill in the blank, (d) select a response provided, and (e) qualitative open-ended test items.

The format for the both MWAT.3 and MWAT.4 were designed to satisfy the following criteria to allow the purpose of creating the MWAT to unfold within the tool.

1. The order of the questioning reflected a typical patient examination: (a) demographics - general information, (b) eliciting a patient history, and (c) conducting the physical examination.
2. Patients were asked questions in a manner they were accustomed, (i.e., using a 10-point rating scale in MWAT.4).
3. The appearance allows for the maximum number of questions in the minimum space. It also allows for repeat, follow-up assessments on the same MWAT.

Methods to Ensure Evidence for Establishing the Validity for the Development of the MWAT

The concept of validity is the principle concern in test development. A brief review of the concept of validity will endorse the process employed to defend its claims. Validity of a test is not a concrete phenomenon. Validity is a process to validate the test inferences rather than it being a direct measurement of the test itself. It is the interpretation of the test scores through inferences drawn from the test results, that are validated, not the test itself. Evidence for validity is supported by evidence for an interpretation of the test scores. Evidence is gathered to support the strength of the claims of validity. There are many methods of gathering evidence to support validity of an inference. The gathered evidence dictates the type of inferences that are appropriately made. Each inference must be supported with evidence. Validity is reported in degrees. A high degree of validity for an inference is supported with a large amount of evidence, while, a low degree of validity results from inferences that are weakly supported with a small amount of evidence.

There were many methods of gathering evidence to support validity of inferences made from the results of the tool. The strength of the evidence gathered dictates the type

of inferences that are appropriately made from the results of this study, as each inference must be supported with evidence. An organized method of developing the MWAT was essential to strengthen the evidence for validity of the test results.

Test items contributed to validity in MWAT.2 by meeting the following conditions:

1. The purpose of the instrument was well defined, which included a precise description of the test's content.
2. The instrument's purpose and content were outlined in a set of specifications.

The method of creating the MWAT.3, MWAT.4, and MWAT.5 encompassed seven essential steps to support validity claims of the items within the MWAT.

1. The congruence between test items and their defined specifications was demonstrated with an organized method. The congruence criterion is the degree of similarity between each item and the test item specifications.
2. Each objective was clearly written.
3. Methods were used to reduce systematic measurement error, reducing bias.
4. The format was designed to be suitable to the test goals.
5. Each item was designed to meet specific technical assumptions. These assumptions included unidimensionality of items (each item contained one concept) and local independence (items were not dependent on each other) of the items.
6. The items were written in a uniform editorial style. They were reviewed for spelling, grammar, punctuation and word usage.
7. The items meet legal and ethical standards. The respective ethic review boards approved the study. The items were not taken from a copyrighted source.

Description of the Participants

There were three groups of subjects included in the development of the MWAT:

1. One hundred and thirty-six experienced health care providers contributed to the content of the MWAT as outlined in Chapter 3 - Preliminary Research.
2. Three expert judges evaluated the MWAT.2. Two oncologists (one from the Cross Cancer Institute, Edmonton, Alberta; and the second from the London Regional Cancer Center, London, Ontario) and one advanced practice nurse (Ontario Cancer Institute, Princess Margaret Hospital, Toronto, Ontario).
3. Two patients with malignant wounds that were over the age of 18.

Sampling Strategy for MWAT Development

1. The sampling strategy for the 136 health care providers contributing to the content of the MWAT was described in detail in Chapter 3 - Preliminary Research.
2. The two oncologists were selected because of their extensive experience in breast and head and neck cancer, which are the sites that most commonly metastasize to skin.
3. The patients' chosen were the first two patients referred to the investigator after the MWAT.2 was prepared, one with breast cancer and the other with head and neck cancer.

Data Collection Strategies for MWAT Development

Data was collected in the following manner:

1. See Chapter 3 - Preliminary Research for data collection from the 136 health care providers.
2. Data was collected from the oncologists and the advanced practice oncology nurse by using the following procedure:
   (a) Each participant was contacted by telephone and asked if they would be interested in evaluating the MWAT.2.

(b) Each participant received an overview of the research proposal to ensure they understood the purpose of creating the MWAT.

(c) The MWAT.2 was e-mailed to each participant with a set of instructions (Table 4.9, Appendix 1, p. 106).

(d) Participants were all asked to evaluate the MWAT by complying with the instructions provided.

(e) Participants e-mailed the responses back.

(f) The investigator did not discuss their responses until all replies were returned.

(g) The selected expert judges were in different cities and not aware of the identity of the other judges at the time of the evaluation.

3. Data was collected from the two patients using the following procedure:

(a) The purpose for creating the MWAT was explained to the patients and consent was obtained.

(b) The usual consultation was replaced with the MWAT.2.

(c) They completed the evaluation the MWAT (Table 4.10, Appendix 1, p. 107).

The comments of the two patients were incorporated in the evaluation of the MWAT.

Method of Analysis of the MWAT Development

The responses from the expert judges and the patients were treated in a similar fashion:

1. The results of the responses were printed. Each individual evaluation was labeled - a, b, c, d, or e.

All similar pages were compiled for comparison (i.e., page 1 from each evaluation was assessed simultaneously).

1. Once the items were altered according to the responses, the principle investigator met with the advanced practice oncology nurse to review the MWAT.2 in detail.
2. The collected data was analyzed.
3. This process drove the MWAT.2 changes to develop MWAT.3.
4. The MWAT.3 was the first instrument in the pilot test.

In summary, transition from MWAT.2 to MWAT.3 was driven by: (a) reviewing the results of the preliminary research (Chapter 3) for highest frequency items (Table 3.1, p. 26), (b) e-mail communication and discussions with the expert judges, (c) ensuring the item specifications were met (Tables 4.2 - 4.7, Appendix 1, pp. 98 - 103), (d) reviewing the item response options chosen for each item (Table 4.1, Appendix 1, p. 97) and (e) including the causes of the patient signs or symptoms, particularly in the physical examination (Table 4.8, Appendix 1, p. 104). The MWAT.3 was the first tool in the pilot test phase.

Instrument Testing - Pilot Testing the MWAT

Pilot testing the MWAT was the process of delivering the MWAT to patients with malignant wounds for the first time and altering the tool until a point of saturation. Initially, there were problems with patient and interviewer interpretation of the test items in the tool. As expected, the wording and formatting of the tool were awkward at times, which lead to the progressive development of MWAT.4 and MWAT.5. The pilot test was complete with the MWAT.5 as changes were no longer necessary to accomplish the goal of assessing patients with malignant wounds as determined by the patients and interviewer, when the point of saturation was achieved (i.e., no new information was found in the data).

The purpose of the next section is to explain the following: (a) the research design including the procedure of administering the MWAT.3 to patients, (b) description of participants including the subject inclusion and exclusion criteria, (c) sampling strategy, (d) MWAT adjustments resulting in versions MWAT.4 and MWAT.5, (e) data

collection, and (f) method of analysis of the pilot test of the MWAT and the evaluations of the MWAT.

Research Design

The MWAT is descriptive, survey research for patients with malignant wounds. The research design outlines the procedure to enter patients into the pilot study. The study was open for patient entry from September 2000 to March 2001.

Procedure

1. Cancer patients with malignant wounds were referred from the oncologists and palliative care teams. The initial contact person was the team that referred the patient for the malignant wound assessment.
2. All patients referred for a palliative medicine assessment of their malignant wounds who met the inclusion and exclusion criteria were offered entry into the study in London, Ontario.
3. A patient was referred to the oncologist specifically for pilot testing the MWAT.5 in Edmonton, Alberta.
4. All patients received a letter of information describing the study and signed a letter of consent. All patients were verbally reassured that their care would not be affected if they chose not to enter the study.
5. Patients were assessed: (a) at the cancer clinic, (b) in the hospital, or (c) at their homes.
6. The patient determined if family members would stay throughout the assessment.
7. The assessment followed the format of the MWAT.
8. The interviewer completed the MWAT by: (a) reviewing the chart and recording information, (b) interviewing the patient and recording the patient's responses, and (c) completing a physical examination and recording the exam findings.
9. Digital images were taken of the malignant wounds.
10. Patients were not offered any incentives for being involved in the study.

11. Patients and interviewers were asked to evaluate the MWAT by responding to the Patient and Interviewer Evaluation of the Malignant Wound Assessment Tool (Table 4.10, Appendix 1, p. 107).
12. Completion of the MWAT, its evaluation and patient management (outside of the study) took approximately one hour per patient.

Description of the Participants

The patient population was defined by clear inclusion and exclusion criteria. These criteria included the clinical diagnosis and basic patient characteristics. It was important that the patient population was narrow enough to focus on patients with malignant wounds, but broad enough to be valid for other studies. A broad, simple definition for malignant wound was used. The malignant wound was defined as; the invasion by cancer into the skin.

Subject Inclusion Criteria

The two inclusion criteria for patients to partake in the study were:

1. Cancer patients with a malignant wound.
2. 18 years of age or older.

Subject Exclusion Criteria

Patients were excluded from the study when, although they met the inclusion criteria, they were disoriented and unable to make their own clinical decisions.

Sampling Strategy

Due to the nature of this study, a convenience sample was drawn from the participating centers. Four centers were invited to enter patients, however, only two centers entered patients. The population was well defined therefore randomization was inappropriate. Patient entry continued until no further changes were made to the MWAT as reflected by ease of administration and patient response to the tool. Juniper et al.,

(1997) supported this method of determining the appropriate sample size for pilot testing a health-care instrument.

Generalizability to the all patients with malignant wounds was dependent on testing the MWAT on a wide range of patients with a variety of malignant wound clinical presentations and varying degrees of symptom severity.

MWAT Adjustments During the Pilot Testing

The MWAT adjustments were determined by the need to: (a) assess a wide range of malignant wound clinical presentations, (b) capture varying degrees of symptom severity, and (c) ensure ease of administration for clinical and research use. The results of evaluating the MWAT drove the modifications to the MWAT. The MWAT was altered until the interview became feasible and comprehensive. Three versions of the MWAT were created and pilot tested, MWAT.3, MWAT.4, and MWAT.5.

The method of altering the MWAT.3 and MWAT.4 to create the MWAT.5 was based on evaluating the results of the previous tool. The results of the MWAT.3 and MWAT.4 are presented here as the method of creating the MWAT.5.

In general the MWAT development required the following adjustments:

1. Decreasing the length of the tool: (a) from MWAT.2 to MWAT.3 and, (b) from MWAT.4 to MWAT.5.
2. Altering the tool format: (a) from MWAT.2 to MWAT.3 and, (b) from MWAT.4 to MWAT.5
3. Changing awkward items: (a) from MWAT.2 to MWAT.3 then, (b) MWAT.4 to MWAT.5.
4. Adding and deleting items: (a) from MWAT.2 to MWAT.3 then, (b) MWAT.4 to MWAT.5.

Altering the MWAT.3 to MWAT.4 included the following changes: (a) the range and anchors, and (b) the grouping test items. The result of these changes lead to the change from MWAT.4 to MWAT.5 as explained below.

The range and anchors used to report patient symptoms changed from: (a) 1 (not at all), 2 (mild / sometimes), 3 (moderate / usually), 4 (severe / all the time) and 5 (does not apply) to (b) 0 (not at all) to 10 (overwhelming). This change was driven by: (a) the recognition that the 1 – 5 rating system in MWAT.3 allowed two interpretations for each symptom, and (b) the interpretation of the results of the patient-interview evaluation.

The 1 – 5 rating system allowed the items to be interpreted as either symptom severity or frequency. The patients had to decide which descriptors applied for each test item. The -- mild, moderate, severe -- descriptors referred to symptom severity or intensity, while the – sometimes, usually, all the time -- descriptors referred to symptom frequency. For example, when the patient was asked, "Does your wound bleed?" they may state that it *sometimes* bleeds *severely*, since both the 2 and 4 ratings would be appropriate and the interview became awkward during this questioning. This difficulty was circumvented by changing the descriptors in MWAT.4 to 0 – 10. This evaluates the intensity or severity of the symptom. In the stated example, the wound *sometimes* bleeds *severely,* the patient would have to integrate two descriptors, but since only one option is permitted, they were able to determine which was more prominent (*sometimes* or *severely*), the interview was not nearly as awkward.

This change in rating scales was also supported by a statement made by one patient during the MWAT evaluation. While reviewing both scales on paper, I asked, "*would it be easier to choose an answer from the 1 – 5 rating scale or the 0 – 10 scale?*" The answer was, "*0 – 10 is OK for emotional questions. It is easier because we already know how to answer that kind of question*". It was decided then that MWAT.4 would use the 0 – 10 rating scale.

Second, the MWAT.4 combined questions within single test items. This was done to allow common themes to be thought of together. The following items had two or three questions within each item:

1. Item 5. Cancer diagnosis and date of diagnosis.
2. Item 7. When did the patient first notice the wound? How much does it change each month?
3. Item 8. Previous radiation, chemotherapy and cancer surgery.

4. Item 40. Has the skin around your wound changed? Rate 0 – 10. Describe.
5. Item 41. Does the wound change your ability to do normal activities? Describe.

However, the result of this change was a loss of unidimensionality of test items. This change resulted in missing data and insufficient white space to record all of the responses. This result was unacceptable and was addressed in the MWAT.5. This was not the only issue that was addressed in the MWAT.5.

MWAT.4 was not entirely independent of MWAT.3. Other than the differences mentioned above, they were quite similar. The text items and the Patient and Interviewer Evaluation of the MWAT were analyzed together. The prominent results of the text items are listed in Table 5.2 (Appendix 1, p. 109) using the numbering in MWAT.4.

The most striking finding of the Patient and Interviewer Evaluations was that the patients universally and overwhelmingly stated: (a) the MWAT was easy to understand, (b) the questions did apply to their problems, (c) enough questions were asked about the wound, (d) the questions were not too difficult to answer, and (e) nothing was left out in the questioning about the wound (although one patient wanted to clarify wound management). These universal results were concerning and raised the suspicion of the Hawthorne Effect described by Shi (1997) as " the reactive effect of research on the social phenomena being studied" (p.7). In this research, it was unclear if patients were responding positively to the MWAT evaluation because it was truly an excellent tool, or because they wanted to please this researcher who was frequently the only physician they encountered who devoted an entire interview to the wound. Attempts to increase objectivity, to reduce the Hawthorne effect were carried out by: (a) leaving the room when the evaluation was completed, (b) allowing patients to compare two tools, (c) reassure patients that their opinion was valuable, and (d) most importantly, record and evaluate observations of the patient while they completed the MWAT.

The most salient observations were recorded on patients 10 and 14 who were both gentlemen with head and neck tumours not concealed under clothing. They both appeared to be coping very well with their situations and had calm, rational personae.

When I asked items 36a and 36b, "Does the wound change the way you look at yourself in general (your self-image) and your body (body-image)?" they both began to cry. Patient 14 stated, "*I would just like to leave this world*", while patient 10 stated, "*I never really thought I was much to look at*". Yet, when they were asked if the questions were too hard to answer in the MWAT evaluation they both said "*no*". Other items did not fit comfortably within the tool. These included: (a) Item 34 "Is it difficult to cope with the wound?" and (b) Item 35 "Are you afraid to look at the wound?"

These test items were identified as prominent concerns for patients with malignant wounds in the preliminary research. However, they have been shown to be too sensitive and too personal to be raised on a first visit to evaluate the wound in general. They are important issues but better left for supportive discussions should patients choose to share that information with a health care provider. As a result of these observations, they were removed from the MWAT.5.

Other observations that tailored the MWAT.5 are listed below:

1. In item 28 "Does the wound change your appetite?" patients had difficulty stating if it was the wound that altered their appetite.
2. Item 42 "What are your daily activities?' was collected as text data. It was meant to derive the patient's ability to function but a second interviewer who tested the MWAT.5 suggested that the KPS score be used in its place. This suggestion was supported by the results of the text data collected on item 42, which revealed a pattern of level of functioning very similar to the categories in the KPS.
3. Concerns identified in the preliminary research, which were not included in the MWAT, were: (a) recording the location of the observed edema during the physical examination, and (b) determining if the health care provider was supportive.
4. The coding sheet was too cumbersome to use in the clinical setting in MWAT.3 and MWAT.4.
5. The tool was too long to be used in routine clinical practice.

Five patients completed the MWAT.4. It was similar to the MWAT.3 and some of the changes were not beneficial. It became clear that the significant changes were required. The MWAT.5 was therefore created.

The results of creating the MWAT.5 are described in length in the Chapter 5 - Results because they are the main results of the entire study.

Data Collection

The MWAT survey was utilized and completed to replace the patient assessment during the consultation. The completed MWAT's were chronologically numbered and stored in a secure file cabinet. The digital images of the wounds were taken with a NIKON 990 digital camera. They were taken at the end of the assessment as a method to document the physical examination. The images were stored on a compact disc and stored in a secure file cabinet.

Method of Analysis

The method of analysis was divided into two phases the: (a) pilot test, and (b) patient and interviewer evaluation of the MWAT.

The Pilot Test

Three versions of the MWAT required evaluation, MWAT.3, MWAT.4, and MWAT.5. Each of the three versions of the MWAT was divided into two Microsoft EXCEL, version 2000 spreadsheets. Each MWAT had spreadsheets for: (a) numerical data and, (b) text data. Numerical data included data from dichotomous, categorical, continuous item responses. Open-ended item responses were entered into the second Microsoft EXCEL, version 2000 spreadsheet as text data.

Descriptive statistics were used to analyze the numeric data. Data were analyzed for gender, age, variation in primary tumours causing the malignant wound, and the presence of physical and emotional symptoms. This was completed to assess the range of patients evaluated by the MWAT. The text data was grouped into themes, and then coded according to recurring themes.

Patients were entered into the pilot test until the addition of patients no longer added to the data collected, to the point of saturation. A total of 24 patients were entered.

Patient and Interviewer Evaluation of the MWAT

The data from the Patient and Interviewer Evaluations of the MWAT was collected immediately following the completion of the MWAT (Appendix 1, Table 4.10 p. 107). Initially, for the MWAT.3, the interviewer read the evaluation items, the patients responded and the interviewer completed the evaluation form. However, the responses were all positive, so the procedure changed. The patients were given the evaluation, the interviewer left the room and the patient completed the evaluations. This did not change the results. Open-ended responses were entered into a spreadsheet using Microsoft EXCEL, version 2000 grouped into themes and coded according recurring comments.

Conclusions

The methods for developing and pilot testing the MWAT were thorough. Psychometric principles in instrument design were clearly followed for an evaluative health related instrument. Multiple progressive phases resulted in five versions of the MWAT. This thorough process was necessary to defend potential claims of validity and generalizability from the inferences drawn from the results of the study.

The results of the MWAT will be presented in Chapter 5 - Results. Like the methods, the results will also be sub-divided into the two phases: (a) the development of the MWAT, and (b) pilot testing the MWAT.

CHAPTER 5 - RESULTS

The results are divided in two primary phases: (a) the development of the MWAT and, (b) pilot testing of the MWAT. The development of the MWAT is further subdivided into MWAT.1 (Appendix 4, p. 116), MWAT.2 (Appendix 5, p. 130), and MWAT.3 (Appendix 6, p. 145) development as well as formatting the various MWAT's. Pilot testing the MWAT is presented by outlining the use of MWAT.3, MWAT.4 (Appendix 7, p. 152), and MWAT.5 (Appendix 8, p. 159) in the field. It was necessary to present some of the results in Chapter 4, Methods, because they were the method of creating the next MWAT in succession. For clarity and completeness this chapter summarizes the results of each MWAT developed. Where the results of an MWAT were mentioned in the Methods section, only a brief overview is provided. However, if the results were not mentioned earlier, in particular for MWAT.5, thorough reports are provided.

The Development of the MWAT

MWAT.1 (Appendix 4)

The MWAT.1 was the initial result in the development of the MWAT. The MWAT.1 was created to present and manage the extensive information uncovered in the item generation phase. It helped satisfy the required step of validly identifying the content for item generation. This process resulted in a significant body of information that was so cumbersome it was necessary to summarize it into a usable format. The MWAT.1 was simply collated information. The next essential step was to create test items based on valid methodology. This step resulted in the creation of MWAT.2.

MWAT.2 (Appendix 5)

The purpose of item generation was to develop a valid method to determine the use of the identified content within the test items of the MWAT. MWAT.1 outlined the summarized content and MWAT.2 resulted from determining the use of the content in the

tool. The MWAT.2 was the second step in item generation for the tool. It was composed of the actual test items.

The MWAT.2 was an all-inclusive, theoretically based tool. It was very long and of very little practical value for clinical use. Expert judges, patients, oncologists and a oncology nurse practitioner assessed the MWAT.2, as described in Chapter 4 - Methods. The results of their evaluation lead to the next stage in MWAT development. In order for it to be of value in the field, MWAT.2 was refined to the MWAT.3.

MWAT.3 (Appendix 6)

The MWAT.3 was the result of transforming the MWAT.2 into a tool designed to be suitable for pilot testing on patients. The MWAT.2 was altered substantially to arrive at the MWAT.3 through item reduction and reformatting of the tool. The MWAT.3 format represented the overall population with quantitative test items and was also well adapted to the individual patient with qualitative, open-ended test items.

The format of the MWAT was identified as the critical link between theory and practice. The format of the MWAT.3 permitted the interview to be conducted in the same manner that patients are typically assessed in medicine: (a) chart review to understand the patients background information followed by, (b) obtaining the patient history with verbal rating and open-ended scales, and then (c) the physical examination. Once MWAT.3 was prepared the second phase, pilot testing the tool, was started.

Pilot testing the MWAT

Pilot testing the MWAT was conducted on patients with malignant wounds in two phases: (a) the MWAT was administered to patients, and (b) the patients evaluated the MWAT. During the pilot testing period, the MWAT was adjusted by: (a) altering the format to produce the final MWAT, (b) adding and deleting items, and (c) changing awkward items. The final MWAT.5 was used until the saturation point. Significant changes were no longer required as mandated in Table 2.3 (Appendix 1, p. 93), to meet the psychometric requirements of pilot testing a tool.

MWAT.3 Pilot Testing

Once complete, the MWAT.3 was offered to the first 10 consecutive patients with malignant wounds referred in London, Ontario, Canada for Palliative Medicine consultations of their malignant wounds.

Ten patients were informed of the study and signed a written consent between September, 2000 and November, 2000. All patients completed the MWAT and the evaluation of the MWAT with the investigator's assistance. No patients declined entry nor refused to answer any of the questions within the tool. Approximately one hour was required to complete the MWAT and its evaluation and provide patient management.

The sample size was determined by the need to alter the MWAT.3 to MWAT.4 to allow the tool to appropriately suit the population. The sample size was not pre-determined. Juniper et al., (1997) described this method of sample size determination as a valid method of tailoring an instrument to the test population during the pilot-testing phase. This method allowed obvious required changes to occur when they appeared.

The MWAT.3 had a total of 73 items. The responses to these were categorized into two groups depending on whether the responses provided were numerical or text in nature. The responses to the Patient and Interviewer Evaluation of the MWAT were recorded as text responses.

Three Microsoft EXCEL, version 2000 spreadsheets were created to analyze the data: (a) MWAT.3 numerical data, (b) MWAT.3 text data, and (c) text data from the evaluation of the MWAT. The results of MWAT.3 numerical data are summarized in using descriptive data and are presented in Table 5.1 (Appendix 1, p. 108). Altering the MWAT.3 to MWAT.4 was driven by the need to simplify the MWAT and by the evaluation responses.

MWAT.4 (Appendix 7)

MWAT.4 was developed while MWAT.3 was still being used. Once significant changes were made to MWAT.3, the MWAT.4 was introduced to patients. The fundamental differences between MWAT.3 and MWAT.4 were: (a) changing the anchors and the range of responses to record the patient's perceptions, and (b) combining

some demographic items into groups. These changes were described in detail in Chapter 4 - Methods, because the results of the MWAT.4 were used as the method to create the MWAT.5.

MWAT.5 (Appendix 8)

MWAT.5 was derived as a result of a cognitive paradigm shift in approaching this project. An entirely new philosophical perspective of approaching the MWAT development and testing was required to eliminate the growing list of concerns with the MWAT.4. It was essential to return to theory to congeal all acquired knowledge to date while striving for a new format to display the desired MWAT content.

The Development of the MWAT.5

Theoretical principles formulated the basis of the MWAT.5. Consideration of the following issues assisted in this new tool development.

1. Review Test Content Specifications
2. Review Item Specifications Tables
3. Resolve concerns with the MWAT.4
4. Create a different format
    a) Review benign wound tools
5. Reduce to a maximum of two pages
    a) General information page
    b) Wound specific information page
6. Eliminate the coding sheet

Test Content Specifications

The test content specifications (Table 4.1, Appendix 1, p. 97) were reviewed. Items removed from the test were; self image, body image, discouragement, appetite and coping.

Item Specifications Tables

The amendments listed in Table 5.3 below were made to the item specification tables.

Table 5 3: Amendments to Item Specification Tables 4.4 – 4.7

Table	Concern	Amendments
4.4	Reduce the number of emotional items.	Excluded: discouragement, coping, body image and self image.
4.5	Appearance of the dressing.	Changed to: open-ended item.
4.6	Granulation tissue describes healing tissue in benign wound.	Describe the appearance of the wound with – pink / red.
4.7	Photograph and digital image.	Treated as one item.

Resolve Concerns with the MWAT.4

There were seven main concerns with the MWAT.4 that required changing:

1. Sensitive items needed to be deleted or changed:
   a. Excluded: discouragement, coping, body image and self-image.
2. Nonspecific items that did not add to the evaluation of the malignant wound were removed:
   a. Appetite
3. Missing items were added:
   a. Examination of edema.
   b. Evaluate the support of the health care provider.
4. Unidimensionality of items was restored.
5. Performance status test item changed from an open-ended text item to a validated KPS score.
6. Repeated, redundant items were removed:
   a. Functional compromise will only be evaluated once.
7. Reduce the length and complexity of the MWAT through a new format.

Create a Different Format

Benign wound tools were reviewed to assess the format of the tools. The Braden scale (Braden, 1997) for predicting pressure sore risk had a potentially usable format although the content would be entirely different.

Reduce to a Maximum of Two Pages

General information, including patient demographics and wound care was placed on page one. The items pertaining specifically to the malignant wound were placed on the second page. This design allowed the second page to stand alone as the specific assessment of the malignant wound. It included the history and physical examination specific to the concerns of the malignant wound.

Eliminate the Coding Sheet

The information from the coding sheet was placed in the context of the MWAT.5. This was done to streamline the MWAT so that it would be a clinically useful tool.

Pilot Testing the MWAT.5

The MWAT.5 was pilot tested on eight patients in London, Ontario, Canada and one patient in Edmonton, Alberta, Canada. All patients completed the study. Five patients had breast cancer and four had head and neck squamous cell carcinoma. The results were very similar to those reported for MWAT.3 and MWAT.4. The Patient and Interviewer evaluations of the MWAT.5 were valuable, especially the data from patient 16.

The data from patient 16 was entered into the study, only once, as the first patient in MWAT.5. However, patient 16 was initially referred in October, 2000 when she completed the MWAT.3. Patient 16 was assessed in follow-up approximately six weeks later, evaluating the MWAT.4. Patient 16 was admitted to hospital approximately two

months later just after the MWAT.5 was created. Patient 16 thoroughly compared and contrasted the MWAT.4 with the MWAT.5. The results are in Table 5. 4 below.

Table 5 4: Patient 16 Comparison of MWAT.4 and MWAT.5

Test Item	MWAT.4	MWAT.5
Were the questions easy to understand?	Yes.	Yes.
Did the questions asked apply to your problem?	Yes.	Yes.
Should I change any of the questions?	I think I really understand what you are doing now. Use MWAT.5.	No, these are good questions – more conscientious.
Did I ask enough questions about the wound?	Too many thinking questions that I thought needed a big answer for.	Better, enough questions and not too many. These are the right questions.
Was it too difficult to answer these questions?	Too long and boring.	No.

The MWAT.5 accomplished all the required changes:

1. Sensitive items including coping, body image, self image and were excluded.
2. Appetite and discouragement were omitted, as they were nonspecific items that did not add to the evaluation of the malignant wound.
3. Missing items were added, including evaluation of the health care provider support and examination of edema.
4. Unidimensionality of items was restored.
5. Functional compromise was only questioned once to remove redundant items.
6. The performance status was changed by: (a) deleting the open-ended test item asking what their daily activities were, and (b) adding the KPS.

7. The length and complexity of the MWAT were reduced. This was accomplished by developing a new format.
8. The coding sheet was eliminated.

The items regarding emotional concerns are frequently emotionally demanding components of any given interview. Yet, they clearly identify patients' concerns. The MWAT.5 significantly reduced, but did not eliminate the emotional test items as compared to MWAT.4. This was deliberate because treatment options are available for these stressful feelings and for that reason it is important to diagnose them. Therefore, general emotional test items belong in the MWAT along with the other items that bring together a global understanding of the patient and their concerns regarding living with a malignant wound.

The MWAT.5 was a tremendous improvement over the MWAT.4. Its simplicity and directness permitted its use within the clinical setting that actually decreased the burden of assessing these patients in general. It was: (a) an improvement over the MWAT.4 as the interviews were more straightforward, and (b) easier to assess a patient with a malignant wound with the MWAT.5 than not to have any tool at all. This second point was determined by my extensive clinical experience of assessing this patient population. Since this was the ultimate purpose for creating the MWAT, the alterations in the MWAT stopped and the MWAT.5 became the final tool.

Photographs, either through conventional photography or digital imaging, have been incorporated into the MWAT. Their real value will be in longitudinally following a patient over time. They do complement the single visit substantially though by identifying the wound location and depicting the described lesion.

The MWAT.5 is two pages in length and it assesses the patients' demographic information as well as the physical, functional, emotional and social characteristics related to the malignant wound. The first page collects general patient information including: (a) patient demographic information; name, gender, date, date of birth, location of the interview and patients institution number; (b) cancer history and treatment is questioned including; cancer diagnosis, date of diagnosis previous and current radiation, chemotherapy, cancer surgery, sites of metastases, date wound first noticed rate

wound changes and the functional ability of the patient with the KPS; (c) wound care is assessed by questioning the; wound care provider, cleansing regime, number of dressings changes, names of all dressings, the importance of the appearance of the wound covering, wound care effectiveness, and previous wound care attempted; and (d) general test items including relevant medical problems, allergies and medications.

The second page of the MWAT.5 is very specific to the patients' experience to living with the wound and the physical examination. It is formatted in landscape and the test items are read across in rows. There are aspects of 19 concerns examined. Items one to five pertain to the patient history and include: (a) pain; during and between dressing changes, sensitivity to light touch and itching; (b) patient descriptions of smell, drainage, bleeding, and swelling; (c) social issues; family support, friends support, health care support, and social isolation; (d) emotional concerns patients' experience including if they are; anxious, depressed, embarrassed, fearful or frustrated; and (e) patients are asked what bothers them the most. The physical examination is recorded in items six to 19. This exam includes: (a) wound classification, (b) description of the wound bed, edges, location, measurements, (c) peri-wound skin, (d) the description and cause of wound odour, exudate, bleeding and the location of edema, and (e) altered function.

Generalizability to the Population of Patients with Malignant Wounds

A total of 24 patients were assessed during the pilot phase of the MWAT. There were several test items that remained the same through all three versions of the MWAT tested, despite the formatting changes. Demographic and symptoms severity item responses that were evaluated during the entire pilot phase were combined to review the distribution of the 24 patients assessed during the pilot-test (Table 5.5) below.

Table 5 5: Generalizability Assessment. The results of combining the demographic and symptom severity responses from MWAT.3, MWAT.4 and MWAT.5 *

Item	Response		
Gender	Female = 16, Male = 8		
Age	Average = 68.67 Range 49 - 86		
Tumour type	Breast = 11		
	Head & Neck = 8		
	Lung = 2		
	Uterus, rectum and lymphoma = 1 each		
Photograph	All patients consented to a photograph		
Symptom Severity	Mild (1-3)	Moderate (< /=5)	Strong (>/=5)
Pain during dressings	13	3	6
Pain between dressings	9	9	6
Burning	14	4	6
Sensitivity to light touch	12	3	8
Itch	11	7	5
Smell	13	7	4
Drainage	7	6	11
Bleeding	13	9	1
Swelling	11	6	7
Anxious	7	6	11
Depressed	7	3	13
Embarrassed	13	4	6

* Note: N = 24, the totals per row are = or < 24 as not all patients had all the symptoms.

Limitations and Delimitations of the MWAT

Although, a considerable effort was made to systematically develop the MWAT, it has its shortcomings that merit mentioning. Limitations to the MWAT stem around the following issues: (a) the vague definition of the term 'malignant wound', (b) measurement bias inherent in survey research, (c) the Hawthorne effect in responding to MWAT items and MWAT evaluations, (d) different interpretations of test items, (e) the weakness of combining quantitative and qualitative research methods, (f) the pilot test was conducted in only two centers, and (g) one researcher entered 23 patients and the

second researcher could only enter one patient in the pilot test phase. The delimitation imposed by the researcher was patients had to be over the age of 18.

The definition of the term malignant wound has not been clearly defined in the literature, this was thoroughly reviewed in Chapter 2 - Literature Review. Since the fundamental purpose of this study was to assess patients with cancer spread to the skin, a patient with cutaneous metastasis referred for symptom management was considered eligible for entry. This issue will be addressed in future research as having a valid assessment tool should assist in identifying the patient population, which could lead to a proper definition of the term 'malignant wound'. For the purposes of this study the term malignant wound referred to; the invasion by cancer into the skin.

Measurement bias occurs in evaluating the importance of an item when over or under sampling of an issue is not addressed within the tool design. Appropriate sampling was considered in the tool design. However, this process may have been biased because the health care providers, rather than the patients, determined the concerns and frequency of occurrence of those concerns. The patient reported concerns might vary from those identified by the care providers. This issue will be addressed in future considerations as the MWAT provides an opportunity to systematically collect patient determined concerns from this population from quantitative and qualitative perspectives.

The MWAT was evaluated through patient and interviewer evaluations. These evaluations were all so similar that the Hawthorne effect may have influenced the responses. This suspicion can be supported on two accounts. First, when two patients were given the opportunity to choose between two different tools they were more critical of the tools than they had previously been. Secondly, patient responses to the MWAT evaluations were at times contradictions to their behaviour during the interview. When this occurred the observation of their behaviour was deemed more important. Typically patients are anxious to please and it is difficult to circumvent this problem. Even when patients were given the evaluation to complete on their own, the results did not change.

As with all questionnaires, the interpretations of the test items may vary between individual patients and examiners. Having the clinician conduct the interview and clarify items as required reduced this error.

The primary weakness of combining qualitative and quantitative methods within one study is that both research methods tend to be used in their most basic forms. This is true for the MWAT. In depth ethnographic technology and advanced quantitative testing of complex hypotheses were not combined. It would be preferable if the level of sophistication of each could have been higher. Yet, it is difficult to heighten this level without the involvement of a team of each paradigm researching the same question.

Although, four cancer centers were invited to enter patients into the pilot test, only two entered patients. One center entered 23 patients and the second center entered one patient. Since the principle investigator has a unique practice established years ago to assess and manage patients with malignant wounds, she was able to have a steady flow of patients into the research. Whereas, the second investigator, although a very experienced oncologist, had not centered out this patient population in the past, and referrals were slower. This patient population is not singled out as a distinct population in most cancer centers. Two cancer centers chose not to enter patients because: (a) one center could not devote time to projects that did not yield project authorship, and (b) the second center was in the USA, and the logistics for ethics approval, and transfer of research dollars were too complicated.

The limitations and delimitations to the MWAT development do not overshadow the qualities it holds. It is worthwhile to summarize the results of this research to recall its value.

Conclusion of the Results

The MWAT underwent developmental and pilot testing phases that resulted in five versions of the tool. Each phase served a purpose and was the foundation for the next version. The final MWAT, MWAT.5, was used and modified until the saturation point. A point of saturation was reached when: (a) the MWAT smoothly blended into the clinical situation assisting patient assessment as reported by the interviewer, (b) it captured the patients' concerns as reported by the patient, and (c) neither the interviewer nor the patient found it intrusive. At that point, it was obvious significant changes were no longer required. It was tested in two centers, the University of Western Ontario and

the University of Alberta at the Cross Cancer Institute. Overall, it was found to capture the patients concerns and function well in the clinical setting.

It was essential to discuss the results within this chapter to the degree required to support the changes from one version of the MWAT to the next. However, a more extensive discussion and the future recommendations for the MWAT are presented in Chapter 6 - Discussions and Recommendations.

CHAPTER 6 - DISCUSSION AND RECOMMENDATIONS

This chapter will review the important principles and the resulting conclusions drawn from the research. It contains a thorough review of its supporting evidence, and includes: (a) review of the objectives, (b) validity and generalizability of the MWAT, (c) similarities and differences with the literature findings, (d) inferences drawn from the MWAT development, (e) speculations on the effects of introducing the MWAT, (g) future recommendations, and (h) final conclusions.

Review of the Objectives

A credible process was used to design the MWAT.5 (Appendix 8, p. 159). This discussion reviews the MWAT.5, as a comprehensive, organized assessment tool for the patient with a malignant wound. Designing the MWAT.5 met the purpose of this research. The process to develop the MWAT.5 included: (a) identifying all concerns that require evaluation in patients with malignant wounds, (b) applying psychometric principles in the development of the MWAT, (c) formatting the MWAT in a manner that makes it usable in the field, (d) pilot testing the MWAT, (e) refining the MWAT until it is acceptable as a clinical assessment tool, (f) analyzing the MWAT through patient and interviewer evaluations, and (g) ensuring the test population represents a wide spectrum of age, tumour origins and symptom severity. A valid process was used to create the MWAT.5.

The responses to the MWAT were not interpreted to describe this patient population for three reasons, the: (a) study was not designed to obtain that information, (b) MWAT changed throughout the pilot test period, so test items were not consistent, and (c) sample size was not large enough to make legitimate inferences regarding patients with malignant wounds. The focus of this study design was to: (a) use a valid process to develop the MWAT, and (b) pilot test the tool on a representative sample of patients with malignant wounds.

The MWAT.5 thoroughly assesses patients with malignant wounds. The first page assesses background demographic information to provide a general understanding of the patient, the wound and tumour treatment and relevant medical problems. The

second page of the MWAT.5 records the patient lived experience and the physical examination. Since the MWAT has the potential of being widely used in multiple countries and settings, it was essential to properly conduct the instrument design process. It is useful to examine and interpret the results of each objective to fully understand the development process of the MWAT.5.

It was important to identify all of the concerns and terms that require evaluation. The term 'malignant wound' defines the patient population the MWAT applies to. A clear definition for the term malignant wound could not be identified in the literature. For the purposes of this study a broad, simple definition was used. The term 'malignant wound' was defined as: the invasion by cancer into the skin.

Patients with malignant wounds have unique concerns that require evaluation. Haisfield-Wolfe and Rund (1997) and Moody and Grocott (1993) report concerns that require monitoring in patients with malignant wounds derived from their case-based experience. Preliminary research, presented in Chapter 3 and Schulz and Triska (1999) provided evidence-based identification of the disease specific concerns to support the anecdotal literature. That research was conducted as a rudimentary portion of this project. The signs and symptoms common to patients with malignant wounds identified were physical signs and symptoms (pain, odour, exudate, bleeding and edema), emotional stress, functional compromise, social concerns and complications (i.e., fistulas and nutritional deterioration). Demographic information, tumour type, gender, age, level of activity, oncology care and dressing treatments were also considered important in patient assessment.

Clarification of disease specific concerns and the frequency of their occurrence advances the literature for patients with malignant wounds. This information was the foundation of the MWAT content. Identifying all the concerns that require evaluation in patients with malignant wounds was a lengthy yet essential phase of the MWAT development. It significantly improved the validity of the process of creating the MWAT. Validly identifying the content of the MWAT was important, yet, insufficient to create a usable assessment tool. Applying well-established psychometric principles of instrument design were necessary to advance this study further.

The second step in the process of creating the MWAT was to apply psychometric principles of instrument development to design the MWAT. This was critical to ensure the MWAT would be created in a valid manner. The psychometric phases were: (a) the MWAT content was accessed from a valid source, (b) tables of item and tool specifications were created, and (c) item generation considered both the content and cognitive processing required to respond to the selected items.

Validity of the outcome of the MWAT development was addressed through following the standard psychometric principles in instrument design. Through the amalgamation of the content identification process and sound psychometric principles, the MWAT was advanced to the MWAT.3, ready for pilot testing. The logical sequence of events used to develop the MWAT was an excellent foundation for the MWAT.3 (Appendix 6, p. 145). The patients in the pilot test could be assessed with the confidence that the tool was sound.

Measurement error was reduced to ensure validity of the process of developing the MWAT in three ways by: (a) accommodating for the frequency of occurrence of identified concerns, (b) ensuring convergence of test and item specifications with the items in the tool and these steps resulted in the creation of the MWAT.1 (Appendix 4, p. 116) followed by the MWAT.2 (Appendix 5, p. 130), and (c) obtaining the opinions of the expert judges who reviewed the MWAT.2 individually and commented on the appropriateness of the items and the tool. This resulted in the development of the MWAT.3. This process ensured the MWAT.3 was developed using a valid method. This was the end of the MWAT development phase. However, development continued in the form of MWAT alterations within the pilot-testing phase of this research.

The MWAT was formatted in a specified manner to: (a) represent the patient-clinician interaction, (b) allow ease of administration, (c) assist the clinician with an organized, thorough approach to these patients, and (d) permit patients an opportunity to describe their unique situation. Major formatting changes were carried out on two occasions. Each format change produced substantial improvements in the MWAT's ability to link the identified concerns with the actual patient assessment, this being the true crux of the entire study.

Pilot-testing of the MWAT was essential to ensure its usefulness in the clinical setting. Pilot-testing permits delivery of the MWAT to the appropriate population for the first time. The interpretation of the results demonstrate that the tool was presented to a wide spectrum of patients with malignant wounds with varying degrees of symptom severity, a variety of primary tumours, with a wide range of ages, and an appropriate distribution between males and females, given that breast cancer is the most common internal malignancy to metastasize to skin. The pilot-test process allowed the discovery of problems with the use of the MWAT in the field. The wording, formatting and, in specific cases, the content of the tool were awkward and did create difficulties. During this pilot-test the patients and interviewers had the opportunity to evaluate the instrument to state their opinion of the tool. This evaluation was critical in altering the MWAT.

The MWAT development from MWAT.3 onwards was driven entirely by the pilot-test results. The MWAT.3, MWAT.4, and MWAT.5 were all introduced to patients with malignant wounds. Each adjustment to the tool was appropriately based on: (a) the interpretation of the test items in the clinical setting, (b) observations of the way in which patients responded, and (c) the patient and clinician opinion of the MWAT.

Change was vital to the valid progression of the MWAT development that allowed changes in items as well as formatting of the tool throughout the pilot-testing phase. The MWAT adjustments were the essence of the pilot test. They were complete once the comments demonstrated that further changes to the MWAT would not provide significant improvements to the tool. This methodical process determined the need to eliminate inappropriate items. Some items were too sensitive while others were too nonspecific. Items relating to self-image, body-image, coping, and fear of visualizing the wound were found to be very positive and appropriately identified as required content. However, they were too difficult and personal to answer on a general questionnaire during the first patient interview. A test item was altered to question the importance of the cosmetic effect of the dressing since potential management included providing socially acceptable dressings in attempt to reduce the effects of self-image. In contrast, patients had difficulty stating the wound directly altered appetite. These identified items were removed from the MWAT.5 and were replaced with an opportunity for patients to comment on individual concerns if they chose to do so using open-ended test items.

Formatting changes also made profound differences in the MWAT on two occasions. The first was when converting from MWAT.2 to MWAT.3 and the second from MWAT.4 to MWAT.5. Each of these formatting changes improved the ease of administration and efficiency in administering the tool. Ease of administration and appropriateness of the items within the tool are essential to the acceptance of the MWAT in the clinical situation.

In summary, the objectives of the MWAT were accomplished. The process of accomplishing the MWAT objectives in a methodical fashion has strengthened the validity and generalizability of the MWAT. This implies that it is capable of capturing the patients concerns, in manner acceptable to the patient and clinician. This discussion of these objectives is in essence a general overview of the research discussion. This chapter will now provide the evidence to support these strong claims in greater detail.

Validity and Generalizability of the MWAT

The purpose of the valid process to create the MWAT.5 was to assess patients with malignant wounds with some degree of confidence that it applied to the entire patient population. It is generalizable to the spectrum of patients with malignant wounds. Acceptance of the MWAT.5 depends on illustrating the extent of the truthfulness of these statements. Therefore the validity and generalizability claims for the inferences drawn from this research are defended to enhance the credibility of the MWAT.

Validity of the Process of Developing the MWAT.5

The inferences drawn as study conclusions are based on the results of the development, pilot-testing and evaluation of the MWAT.5. This discussion on the validity of the MWAT.5 will be guided by: (a) a list of the test inferences, and (b) the evidence to support those inferences.

1. Signs and symptoms common to patients with malignant wounds have been identified by adhering to the valid process of tool development as supported by the following evidence.
    a. The MWAT has content related evidence for validity. The content was pooled from the preliminary research surveying 136 experienced

health care providers, the literature, and personal experience assessing patients with malignant wounds. Expert judges and patients verified this information to ensure its accuracy.

2. Appropriate test items were created by adhering to the valid process of tool development as supported by the following evidence.
   a. When the content for the items was initially selected a number of considerations were kept in mind to ensure congruence between what was measured and what was intended to be measured. These considerations included reviewing; precise subject matter, and the goals for the MWAT.
   b. The relationship between the item content and patient assessment is complex. Organized strategies were in place to transform the content information into appropriate test items to reflect the purpose of the MWAT assessment, by creating Table 4.8, (Appendix 1, p. 104) to assist in directing item development.
   c. The cognitive process demanded of the patients and interviewers were considered in creating the test items.
   d. Each item was designed to meet specific technical assumptions. These assumptions included unidimensionality of items and local independence of the items.
      i. Meeting the assumption of unidimensional test items was a desired goal. An attempt to examine one and only one construct per item was carried out. However, the assumption of unidimensionality can never be completely satisfied because there are too many unknown and uncontrollable factors that can affect the patient's response. It is impossible to be absolutely certain that a specific response was because of a pre-determined construct.
         1. Uncontrolled or unknown factors include: (a) the patients relative reference to the question asked (for example, the symptoms might be severe, but if they were worse earlier the patient may report mild symptoms despite the symptom

severity), (b) test anxiety, and (c) the tendency to answer in a socially acceptable manner.

ii. The assumption of local independence for test items was considered. Local independence presumes that a patient approaches each test item as a unique item, not influenced by knowledge acquired from responding to another item.

3. The MWAT.3, MWAT.4 and MWAT.5 were appropriate to administer to the patients in the pilot test phase of instrument development. This claim is supported by having adhered to the valid process in tool development as demonstrated by the following evidence.

a. A set of specifications for the MWAT as a test and the items within the MWAT were completed prior to item development. These were consistent with the purpose of the MWAT.

b. The MWAT has content related evidence for validity (as validated above).

c. Organized strategies were in place to transform the content information into appropriate test items to reflect the purpose of the MWAT assessment.

d. The test content specification table for the MWAT identified the content domains, processes to approach the content and the importance of each identified domain (major content group). The test content specifications are completed to "focus on precision in language to aid understanding so that test items may optimally reflect their objective" (Osterlind, 1998 p. 73).

e. The validity of the test item construction in the MWAT was examined through analysis of the MWAT.2. This was completed by: (a) experienced judges, (b) two patients, (c) two oncologists, (d) an oncology advanced practice nurse specialist, and (e) a palliative medicine physician.

f. Triangulation for the validity of the tool was obtained by evaluating responses from these five stakeholder groups. This was completed to

ensure the: (a) MWAT was readable, (b) wording was acceptable, (c) test items were appropriate, and (d) format was useable.

g. The cognitive process demanded of the patient and interviewer was also considered.

h. A high degree of similarity between each item and the test item specifications was considered essential to satisfy the congruence criterion. The congruence criterion was based on the development of test items that matched clearly defined test and test item specifications. Each item matched a defined objective within the specifications. Each objective was clearly written so that the item pool could be identified.

i. This process of directly relating the patient concerns to domains included in the MWAT was completed to strengthen the content validity of the tool.

In summary, the test and test item specifications within the MWAT comprised of delineating the appropriate content, the cognitive process of responding to the test items, as well as the organizational display of the content to meet the intended goals of patient assessment.

4. Pilot-testing to evaluate the MWAT.3 and MWAT.4 permitted valid alterations to the MWAT to create the final product of the MWAT.5. This claim is supported by having adhered to the valid process in tool development as demonstrated by the following evidence.

   a. Alterations to create the MWAT.5 were driven by the patient and interviewer evaluations of the MWAT.3 and MWAT.4. The evaluations focused on clarity of questions, ease of administration, patient burden, and representation and relevance to assessing patients with malignant wounds. As a result: (a) inappropriate items were removed, (b) missed items were added, and (c) formatting was changed for ease of administration.

5. Patients and health care providers agree that the MWAT is clinically useful. This claim is supported by having adhered to the valid process in tool development as demonstrated by the following evidence.

a. The pilot study of MWAT.5 was evaluated by patient and interviewer evaluations.
    i. The patient evaluations focused on clarity of questions, ease of administration, patient burden, and representation and relevance to assessing patients with malignant wounds. Patients stated it was acceptable and addressed their concerns.
    ii. The MWAT.5 was tested by two of the investigators (the researcher and an oncologist at the Cross Cancer Institute) and both agree that it is a clinically useable tool.

6. The application of the MWAT is generalizable to the range of patients with malignant wounds. This claim is supported by having adhered to the valid process in tool development as demonstrated by the following evidence.
    a. Clearly defined purpose and content allow interpretation of test scores that are generalizable to the population of patients with malignant wounds.
    b. The 24 patients within the pilot test of the MWAT had a wide distribution of age, gender, tumour type and symptom severity and it was useful for those with mild, moderate and severe disease.

7. Terminology for assessing patients with malignant wounds is inherent in the tool. This claim is supported by having adhered to the valid process in tool development as demonstrated by the following evidence. The terms were comfortably used in the pilot-test. However, the evidence for validity requires strengthening.
    a. The MWAT uses the disease specific terminology that describes the patient concerns. The terms used have been designated as representative terms to express the patient's problems.
    b. The terminology within the MWAT was derived from the literature, preliminary research, and the researchers personal experience treating these patients.

c. The criteria used to determine the terms used in the MWAT were not well developed. The terms vary between descriptions of the patient concerns and diagnosis. This may or may not be appropriate. Yet, this will have to suffice until the patient population is better understood.

8. The MWAT maybe a clinically useful guide for health care providers with and without experience examining patients with malignant wounds. This claim is supported by having adhered to the valid process in tool development as demonstrated by the following evidence. However, there was evidence absent.

   a. The MWAT was designed to guide health care providers with variable levels of experience through an assessment of the patient with malignant wound. It is a self-explanatory instrument.

   b. The strength of the instrument design provides significant evidence that the tool has the potential to be usable in the field.

   c. It requires strengthening through future research by having multiple examiners in multiple settings trial the tool.

9. The MWAT.5 is ready for field-testing. This claim is supported by having adhered to the valid process in tool development as demonstrated by the following evidence (the summary of support for this validity claim is written here and in - item 10 to avoid repetition).

   a. The instrument development process applied in this research followed stringent criteria. As a result the MWAT.5 can be employed with a high degree of confidence in field-testing to determine the validity and reliability of the tool.

10. The MWAT.5 was created in a valid manner to assess patients with malignant wounds. This claim is supported by having adhered to the valid process in tool development as demonstrated by the following evidence. This list supports the MWAT.5 as tool rather than just good test item development, as listed above. Therefore, even at the risk of apparent duplication of information from above, the following list was made to

defend the validity and generalizability of the MWAT.5 as a tool, not just as the sum of its test items.

a. The method of instrument development followed the essential steps to support validity claims of the MWAT.5.
   i. The purpose of the test was well defined. This included a precise description of the test's content.
   ii. Each objective was clearly written so that the item pool could be identified.
   iii. Congruence criterion, the degree of similarity between each item and the test item specifications, was based on the development of items that matched clearly defined test and test item specifications. Each item matched a defined objective. The congruence between test items and their defined specifications was demonstrated through an organized method.
   iv. Methods were used to reduce systematic measurement error and to reduce bias. The number of items representing each specification were counted to decrease the chance of over- or under-estimating the population parameter. This supports MWAT.5 validity.
   v. The format was designed to be suitable to the test goals of assessing patients with malignant wounds using a typical clinical assessment interview style.
   vi. Each item was designed to meet specific technical assumptions. These assumptions included unidimensionality of items and local independence of the items.
   vii. The items were written in a uniform editorial style. They were reviewed for spelling, grammar, punctuation and word usage.
   viii. Items meet legal and ethical standards. The respective ethic review boards approved the study. The items were not taken from a copyrighted source.
   ix. Precise item construction is in itself evidence for test validity.

11. The interpretations of the test scores can be carried out on a per item basis and or collectively based on the entire MWAT. This claim is supported by having adhered to the valid process in tool development as demonstrated by the following evidence.
    a. The pre-determined purpose and item specifications provide justification to interpret the MWAT performance on a per item and per test basis.

Evaluation of the MWAT indicates that the instrument is measuring what it set out to measure. This can be stated with a degree of certainty because the process of creating the MWAT followed the conditions and criteria for validity of test development. This was accomplished by stating a clear purpose for the test development, identifying the test content, demonstrating the congruence criterion, minimizing the systematic error, pilot testing and evaluating the MWAT.

Systematic Error within the Development of the MWAT

A systematic approach to reduce the measurement error in the development of the MWAT was addressed by ensuring: (a) appropriate representation of population parameters, and (b) the strength of the item-objective congruence.

Systematic error was reduced by verifying that the number of items for the population parameters were similar to the representation of that parameter in the MWAT. This was done to avoid over or under representation of the parameter. For example, pain was the most common symptom identified and variations of pain are questioned in five items. Emotional concerns were the second most common symptom and they are examined in five items. Odour, exudate and bleeding are questioned three times each; once, to have the patient describe the severity of the symptom and twice in the physical examination to record the examiners observations.

Congruence criterion is the most important step in demonstrating validity of test development (Osterlind, 1998). It is demonstrated by showing item-objective congruence, which demonstrates the strength of the relationship between the item and the objective as outlined in the Test Item Specification Tables. This ensures *that which is*

actually measured is what *was intended to be* measured as outlined in the item objectives. This was of paramount concern during the MWAT item development and the Tables 4.2 to 4.8 (Appendix 1, pp. 98 - 104) were followed very closely during the development of the test items to be included in the MWAT. The strength of this association directly affects the interpretation of the MWAT and it is integral in gathering evidence for validity.

Determining the strength of the item-objective match was a challenge. It required knowledge of the full implications of the item objective and the medical approach to the patient. Table 4.8 (Appendix 1, p. 104) was designed specifically to assist in this process. The following discussion details the way in which item-objective matching was taken into consideration to assess odour. Three items addressing odour were placed in the MWAT. One item instructed the patient to decide the amount of odour they perceived between 0 (not at all) and 10 (overwhelming). The objective of this item was to address the patient perception of symptom intensity. The remaining two items were designed for the interviewer in the physical examination to describe the symptom severity from the clinicians perspective, and secondly to attempt to determine the cause of the odour. The test items are: (a) odour – describe: na (na = not applicable), under dressing, near patient, moderate odour, strong odour and a blank to describe the unique patient and (b) odour – cause: na, necrotic tissue, infection, exudate and a blank to describe the unique patient.

Odour was assessed from three perspectives: patient determined intensity, the interviewer description, and the cause of the symptom. These three perspectives attempt to strengthen item-objective congruence of measuring odour. The *items* that question *odour* are meant to be *congruent* with the *objective* of evaluating physical symptoms common to patients with malignant wounds as outlined in Table 4.3 (Appendix 1, p. 99) and more explicitly in Table 4.8 (Appendix 1, p. 104). This approach exemplifies the item-objective congruence used throughout the MWAT. This very clearly strengthened the evidence validity of the development of the MWAT.

Triangulation is the use of multiple research strategies to strengthen inferences (conclusions) made in a research endeavor (Shi, 1997). Embedded in this research design is a combination of several research methods: (a) combining qualitative and quantitative research styles, (b) multiple data sources, (c) opinions of several different evaluators and

patients, and (d) the single set of data obtained in this study is interpreted from multiple perspectives. This cross-validation approach demonstrates triangulation.

Generalizability of the MWAT

The inferences drawn from this research are generalizable to the population of patients with malignant wounds. The generalizability claim was innate within the development process itself. First, the content of the MWAT was derived from preliminary research based on 136 patients with malignant wounds. Second, the literature was thoroughly reviewed to understand this population, and the information was incorporated into the test items. Third, experts, including patients, reviewed and commented on the tool content. Fourth, quantitative survey methodology is typically generalizable to a wide population as it results in factual, reliable outcome data. It was chosen in combination with qualitative research to develop this valid, generalizable and unbiased measurement tool. Fifth, the 24 patients in the pilot test mirrored the literature representing the designated population of patients with malignant wounds. And sixth, the range of symptom severity in the 24 pilot patients revealed a full spectrum of patients ranging from mild to severe in symptomatology. All patients stated that the test items in the MWAT were appropriate for them.

The range in symptom severity caused by the wound demonstrated the patients in the pilot study were a representative sample of the population of patients with malignant wounds. Table 5.5, generalizability assessment, demonstrates that a range of mild, moderate and severe symptoms were reported for pain (with dressings, between dressings, burning, sensitivity to light touch and itch), odour (smell), exudate (drainage), bleeding, edema (swelling), anxiety, depression, embarrassment and frustration.

This representative sample of patients in the pilot-test drove the changes from the MWAT.3 through MWAT.4 and finally to MWAT.5. The patient population focused on the concern of interest. Yet, it was broad enough to be valid for the general population of patients with malignant wounds for clinical and research endeavors.

Similarities and Differences with the Literature Findings

The MWAT.5, as a distinct entity, is a valid assessment tool, but it is worthwhile examining whether it is consistent with the literature. Its consistency with the literature will be examined from three perspectives: (a) the appropriateness of the content of the MWAT, (b) the psychometric principles chosen in relation to other health related questionnaires and (c) the format chosen in relation to benign wound care assessment tools.

The content within the MWAT.5 is in harmony with the literature on patients with malignant wounds. In particular, Haisfield-Wolfe and Rund (1997), Moody and Grocott (1993), and Grocott (1995a, 1995b) clearly outlined that a thorough approach to patients with malignant wounds is necessary. They stated the content should be included in the evaluation, based on their clinical experience. The MWAT.5 is consistent with their recommendations because they were reviewed and included in the item generation phase of the MWAT development.

The psychometric principles for developing health related quality of life instruments have been identified in the literature including: Crocker and Algina, (1986); Guyatt et.al., (1993); Juniper et al., (1996); Juniper et al., (1997); Osterlind (1998); Shi (1997); Steckler (1989); Steckler et al., (1992); and Streiner and Norman, (1995). They differ, in some respects, from constructing tests for testing an education process. Evaluating test development from an education perspective constitutes the main body of literature in instrument design. It was important to utilize the concept of validity from this literature. However, health related instruments have unique differences that separate it from the educational literature. The phases identified as essential developmental steps have been utilized within this project. The MWAT is an indirect measure of multiple psychological constructs. Most disease specific tools focus on multiple areas of dysfunction that occur as a result of developing the disease in question. These areas of dysfunction are physical, emotional, social, occupational issues. The MWAT deals with the physical, emotional and social issues. It only addresses occupational issues indirectly by assessing the patients actively level and their functional limitations.

Survey research is a typical method to evaluate health. Combining quantitative (direct measurement) and qualitative (indirect measurement) strengthens tools. The

MWAT integrated the two research paradigms. This allows direct evaluation of the patient while evaluating the internal dynamics between the patient and the disease. Qualitative and quantitative methods are based on different philosophies. The research assumptions are different but complimentary and the limitations of each are compensated by the strength of the other (Steckler, 1989; Steckler et al., 1992). This concept strongly supports the interdisciplinary methodology approach. The psychometric necessities of a high degree of knowledge regarding content, measurement and language mechanics were demonstrated. The MWAT construction was consistent with the psychometric literature in health related quality of life measures (Osterlind, 1998).

While formatting is a psychometric issue, it also must be considered in the context of clinical practice. Appropriate formatting was seen as the pivotal method of connecting the mass of information summated in the MWAT.2 with the patient during the interview process. Communication between the patient and the interviewer is absolutely essential to illicit valid interpretations of the results. Formatting the MWAT determined the arrangement of items within the tool, the response options, organizational framework, font, font size, white space, number of items, and pages. Irrelevant words and those with double meaning were discarded. Opinions, feelings, offensive language and suggestive language were avoided.

Appropriate selection of response options was important. For symptoms that frequently occur in patients (i.e., pain, odour, exudate, bleeding, edema, anxiety, depression and embarrassment), it would be meaningless to record if the symptoms were present or absent. Rather it is the intensity of the symptom that is deemed important. The interval 10-point descriptive scale with sufficient gradations was used in the MWAT.5. This scaling registers within-patient change in preparation to the next research endeavor, measuring within-patient change through longitudinal patient monitoring. Open-ended test items were selected when the range of possible answers were not well defined and individual answers were important for clinical care. They broadened the understanding of this patient population. This process allowed clarity of expression within the tool. Consideration was given to the formatted presentation of the chosen items to successfully meet the desired goal. The goal was to produce a thorough, yet clinically, acceptable tool for routine clinical and research use.

The health care provider comfort level in using the tool will have an effect on the acceptance of the MWAT. This will influence the widespread use of the MWAT in clinical practice. The MWAT format allows the clinician to conduct a patient evaluation using the general principles of patient evaluation: (a) general review of demographic information, (b) obtaining a history and (c) completing the physical examination. An important concept in the MWAT development was that the flow of a typical patient – clinician interaction should not be interrupted.

Health care providers designated to evaluate patients with malignant wounds are frequently familiar with benign wound assessment tools. It is reasonable to believe that if clinicians recognize visual similarities with benign wound tools and the MWAT, they would be more likely to use it. The general appearance of the Braden scale (Braden, 1997) was used as model to outline MWAT.5 in the hope of increasing acceptance of its widespread use.

Brevity of the MWAT is another important issue addressed in the format of the MWAT. It is important that the tool is thorough but also brief, otherwise tired patients and busy clinicians may find it too cumbersome for clinical practice. The MWAT was scaled to briefer tools in two steps, MWAT.2 to MWAT.3 and again during the conversion from MWAT.4 to MWAT.5. The formatting of the tool was dealt with from both psychometric and clinical perspectives. It is worth summarizing the inferences drawn from this research and speculating the effects of introducing the MWAT into clinical use.

The Inferences Drawn from the MWAT Development

The evidence and strength of the validity of these inferences has been outlined in great detail. However, it is worthwhile to review the inferences to appreciate all that was accomplished through this research.

1. The MWAT.5 was created using a valid process to assess patients with malignant wounds. This will help identify the patients lived experience in relation to their wound.
2. Signs and symptoms common to patients with malignant wounds have been identified.

3. Appropriate test items were created.
4. The MWAT.3, MWAT.4 and MWAT.5 were appropriate to administer to the patients in the pilot test phase of instrument development.
5. Pilot-testing to evaluate the MWAT.3 and MWAT.4 permitted alterations to the MWAT to create the final product of the MWAT.5.
6. Patients and health care providers agree the MWAT is clinically useful.
7. The application of the MWAT appears to be generalizable to the range of patients with malignant wounds.
8. Terminology for assessing patients with malignant wounds is inherent in the tool.
9. The MWAT is a clinically useful guide for health care providers with and without experience examining patients with malignant wounds.
10. The MWAT.5 is ready for field-testing to evaluate the validity and reliability of the tool.
11. The interpretations of the test scores during the field-testing can be carried out on a per item basis and or collectively based on the entire MWAT.

Speculations on the Effects of Introducing the MWAT

The reasonable speculations, listed below, are being made on the assumption that the tool is introduced into the field prior to field-testing. There is merit in reviewing the potential outcomes of this project as a stand-alone endeavor:

1. The MWAT can be used assess patients with malignant wounds.
2. Health care providers can use the results of the tool as a method of communication using the standardized terminology.
3. Health care providers will have greater confidence when assessing malignant wound patients.
4. The formalized assessment may increase interest in management.
5. The MWAT will increase the credibility of research in this patient population as a MWAT.5 might be used as a valid outcome measure to longitudinally monitor patients.

The MWAT can change patient-clinician interactions in a number of ways. First, the MWAT is a process to assess the patient's experience and the malignant wound. Second, it may result in identification of the patient's concerns, which often become the focus for care to improve their quality of life. Third, it outlines uniform terminology that assists in communication between health care providers. Fourth, the results offer potential research opportunities to advancing patient management.

Future Recommendations

The MWAT, like most health related quality of life tools, is being developed along a continuum. The MWAT.5 represents substantial progress along its own trajectory and is the groundwork for the next phase of research. It would be ideal for subsequent protocols to encompass field-testing of the tool.

First, the field trials should determine if the MWAT is valid and reliable. Validity testing would focus on the appropriateness, meaningfulness and usefulness of specific inferences made from the test scores. It is important to determine the MWAT's responsiveness to change, that is, to determine if it is able to detect small within-patient change over time to analyze longitudinal construct validity. It is an approach to determine if the MWAT records changes in the patient who is being followed over time. Reliability indices should be calculated to determine the standard error of measurement inherent in the MWAT.

Second, it would be beneficial to develop a process to interpret the MWAT test scores. A scoring system to summarize the results of the test for interpreting the results might significantly enhance its use clinically and in research.

Third, the MWAT offers an opportunity to standardize terminology used when reporting these patients. Standard terminology provides a means of communication between health care providers. This offers an opportunity to develop a definition of a malignant wound and a malignant wound classification system, which would strengthen the terminology used to assess these patients. Patients use verbal rating scales to report their symptoms within the MWAT.5. The MWAT validity and reliability field-testing provides an opportunity to support this method of obtaining patient information. This

might encourage more formal discussions, which typically leads to improved patient care and research conducted on the identified patient population.

Fourth, the development of the MWAT may encourage future research for this patient population using it as an treatment outcome measure for wound measurement, dressings, oncology care and palliative care.

Fifth, it is an opportunity to systematically collect data from a patient perspective. Health care providers determined the MWAT content. It would be worthwhile to examine the responses to test items in attempt to understand this patient population more thoroughly.

Conclusion

A valid process was used to develop the MWAT based on the ample evidence of validity presented in this discussion. The MWAT is a solid foundation in assessing patients with malignant wounds and was created using sound psychometric principles of tool development. However, additional work is required with a larger population to continue to strengthen the tool. This future research will determine the validity of the inferences drawn from the use of the tool and permit the calculation of reliability indices.

Given a greater understanding of the patient's perspective, symptom management for patients with malignant wounds has the potential to alter conventional oncology care. In theory, the MWAT could guide the assessment of these patients and aid in the management process as treatment goals can be based on the patient's assessment. Symptom reduction should be considered whether or not curative oncology interventions are planned.

The MWAT is one example of change in health care focus at the end of life. It is an important starting point to improve the quality of life for patients living with malignant wounds. It is extremely important that health care advances focus on improved end-of-life care as the population ages and people are living longer with chronic progressive illnesses causing significant deterioration quality of life.

The MWAT is a survey that heightens the awareness of the concerns patients with malignant wounds experience. Evidence was organized in a comprehensive, yet

relatively brief survey that blends qualitative and quantitative questioning. It has been designed to capture the patients lived experience and monitor this patient population providing an opportunity to improve the understanding of them. The MWAT has the potential to change the standard of care for patients with malignant wounds as the gold standard assessment tool for patients with malignant wounds.

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APPENDICES

APPENDIX 1

TABLES

APPENDIX 1 - TABLES

Table 2 3: The Steps in Instrument Development and Testing

Stage	Details	Evaluative Tools
Development	Specifying measurement goals	Identify the primary purpose. Prepare test specifications. Identify all items of impairment that might be important to patients.
	Item generation	Select the most frequent and important items.
	Item reduction	Delete non-responsive items.
	Questionnaire formatting	Response options with sufficient gradations to register within-patient change.
	Validity of instrument development	Ensure the tool development and testing has been conducted in a manner that enables valid interpretation of the tool results.
Testing	Pilot testing	Pilot test the tool to ensure items and format are appropriate and practical Alter the tool based on the use of the tool.
	Patient and interviewer evaluation of the instrument	The target population comments on the tool designed for them.
Field Testing	Responsiveness	Able to detect small within-patient change over time.
	Validity of the instrument	Longitudinal construct validity.
	Interpretability	Interpreting the results of participant entry.

Table 3 2: Symptoms Themes Identified From The Survey Responses

Symptom Categories	Descriptors Grouped Together to Comprise the Symptom Theme
Pain	pain intensity –pain, discomfort, irritation, pressure, tightness, severe pain quality- sensitivity- tactile sensitivity, unable to wear undergarments, burning, stabbing, muscle pain, heat sensitive, pruritus – itch, itchiness, itching timing of pain - with dressing changes, pain between dressing changes, pain with movement pain with associated problems - lymphoedema, infection, emotion total pain
Emotional stress	psychological depression, discouragement - a new one every day, despair, grief fear of - bleeding, bleeding to death, total replacement by cancer, dehiscence, fear with visualizing tumor anxiety, worry, frustration, existential distress, coping issues, anger mental fatigue altered self image - disfigurement, body image altered, creepy, dirty, rotting, eating away at humanity, ugly, patient refuses to look at it, poor self image self esteem - loss of dignity, decrease quality of life denial, embarrassment psychological effect of lesion - constant reminder of cancer growth, unable to look at wound, cosmetic/esthetic/visual distress, emotional impairment
Odour	intensity - pungent, malodorous, foul, dizzy & fainting due to odour cause - due to sloughing necrotic tissue, infection, foul smelling drainage infection - heat, fever, chills, odour, bleeding

Table 3 2: Symptoms Themes Identified From The Survey Responses

Symptom Categories	Descriptors Grouped Together to Comprise the Symptom Theme
Exudate	weeping, discharge, drainage, oozing quantity - dry, copious quality - serious, serosanguinous, purulent, corrosive
Bleeding	patient characteristics – coagulopathy, bleeding, vascular, hemorrhage, anemia, friable tumor bleeding iatrogenic bleeding - with dressing changes, anticoagulation
Functional compromise	immobility, movement restriction of extremities, joints, loss of mobility, fusing of arms, decreased range of motion, decreased mobility arm and shoulder, muscle tension difficulty finding position to sleep difficulty - talking, eating, drinking, swallowing, speech compromised, drooling, blindness, tumour growth interferes with vision, deafness, facial palsy, shortness of breath, numbness, heaviness, physical fatigue
Social concerns	social isolation, withdrawal from family and friends, loneliness, isolation, confinement, acceptance in society, decreased sexuality, decreased intimate contact, shunned dependency - not capable to care for self, need to depend on mother as a caregiver limitations - inability to continue with usual responsibilities, recreation - care for others, carrier, social events reactions of others - effect on family, visitors, caregivers, embarrassment with family, care providers, effect on health care provider-dramatic, impatience of some nurses due to time to change dressing, emotional distress related to time nurses had to spend doing dressings
Edema	edema - swelling, swollen arm, leg, lymphoedema

Table 3 2: Symptoms Themes Identified From The Survey Responses

Symptom Categories	Descriptors Grouped Together to Comprise the Symptom Theme
Complications	Incontinence - stool, urine, very difficult to keep clean, incontinent almost continually, stool oozing fistula formation, drainage, corrosive exudate, sinus drainage, fistula drainage - gangrenous, foul copious exudate infection - fever, chills, odour, bleeding, exudate, erythema, maggots fatigue, weakness, physical, mental, pallor nausea, cachexia/anorexia, decreased appetite

Table 4 1: Test Content Specifications

Domain Description of major group	Subordinate group Content of major group to be sampled	Item format	No. of items
Descriptive information.	Institution, age, gender, tumour origin, previous treatment, other sites of metastasis, allergies, medications, wound care provider, dressing changes, dressings.	Fill in the blank.	21
Subjective evaluation of the physical symptoms.	Pain, pruritus, burning, sensitivity to touch, odour, exudate, bleeding, edema, mobility, functional compromise, skin surrounding the wound, daily activities.	Rating scale Fill in the blank.	13 2
Subjective evaluation of emotional issues.	Anxiety, discouragement, depression, embarrassment, frustration, self image, body image changes, coping, fear, importance of the dressing appearance. Most bothersome concern overall.	Rating scale Fill in the blank.	10 1
Subjective evaluation of social concerns.	Social isolation, support of family members, friends, health care providers.	Rating scale	4
Objective evaluation of the physical examination of the wound.	Wound location & classification, odour, exudate, bleeding, incontinence, fistula, periwound skin, size, description of the wound, functional compromise.	Select response. Fill in the blank.	19
Procedures to examine the wound.	Digital imaging, photograph, tracing.	Select an answer.	1

Table 4 2: Test Item Specifications: Descriptive Information

Domain	Demographic information. Previous treatments, radiation, chemotherapy, surgery, wound care.
Skill	Interviewer: Find the information by reading patient records or asking the patient. Patient: Respond to the question.
Item format	Fill in the blank. Select a response.
Item type A	Record patient information that will not change over time: name, chart number, tumour type causing the wound, previous medical problems, allergies, date the wound was first noticed, medications on initial assessment, cancer treatment summary (radiation, chemotherapy, surgery, past wound care).
Item type B	Record patient information that will change over time: date of examination, treatment for the wound, radiation, chemotherapy, dressings, medication.

Table 4 3: Test Item Specifications: Subjective Evaluation of the Physical Symptoms

Domain	Ask patients the significance of the symptom from their perspective.
Skill	The interviewer must read the question to the patient. The patient must: a. comprehend the question. b. interpret the question. c. apply the question to their own situation. d. apply their situation to the given rating scale. e. select a response.
Item format	Rating Scale Fill in the blank.
Item type A	Give the patient a pre-set range (0 to 10). Determine the severity of the symptom to them. One or two questions will be asked for each symptom. Each question will clearly state symptoms are relating only to the wound and the surrounding skin. The following symptoms will be covered: pain, itch, burning, odour, exudate, bleeding and swelling.
Item type B	Ask patients if the wound causes a functional compromise. The interviewer will write down the patient's specific problem.

Table 4 4: Test Item Specifications: Subjective Evaluation of Emotional Issues

Domain	Ask patients the significance of the symptom from their perspective.
Skill	The interviewer must read the question to the patient.
	The patient must:
	a. comprehend the question.
	b. interpret the question.
	c. apply the question to their own situation.
	d. apply the given categories to represent their situation.
	e. choose an answer.
Item format	Rating Scale
	Fill in the blank.
Item type A	Give the patients a pre-set range (0 to 10).
	Ask the patient the importance of the symptom to them.
	One question will be asked for each symptom.
	The emotional issues addressed will be anxiety, discouragement, depression, embarrassment, frustration, fear, coping, change in body image, change in self image.
Item type B	Fill in the blank.
	Answer the question: "What bothers you most about the wound?"

Table 4 5: Test Item Specifications: Subjective Evaluation of Social Concerns

Domain	Ask the patient their perspective of the social changes that have occurred as a result of the presence of the wound.
Skill	The interviewer must read the question to the patient. The patient must: a. comprehend the question. b. interpret the question. c. apply the question to their own situation. d. apply the given categories to represent their situation. e. select a response.
Item format	Rating Scale
Item type A	Patient selects a response from a pre-set range (0 to 10) to determine if: a. family, friends and care providers are supportive. b. they feel isolated. c. the appearance of the dressing is important.

Table 4 6: Test Item Specifications: Objective Evaluation of the Physical Examination of the Wound

Domain	Recording of the physical examination.
Skill	The interviewer performs the physical examination and records their findings on the Malignant Wound Assessment Tool (MWAT).
Item format	Select a response. Fill in the blank.
Item type A	Observe and record the findings on a standardized scale to indicate the intensity of the sign. The following signs will be observed: a. odour and its cause. b. exudate: quantity and quality. c. bleeding and its cause.
Item type B	The interviewer selects a response and fills in the blanks. Description of the wound bed: exposed tumour, nectrotic tissue, eschar. Description of the peri-wound classification. Description of the type of wound classification. Indicate the location of the wound by selecting a response.

Table 4 7: Test Item Specifications: Procedures to Examine the Wound

Major group	Documentation of the wound appearance.
Skill	Trace the wound or take a photograph.
Item format	Fill in the blank.
Item type	Select a response.
	State the procedure to examine the wound, tracing, photograph, digital image.

Table 4 8: Directed Assessment Will Assist in Deciding an Approach to Wound Management

Symptom	Cause of the Symptom	Description
Pain - discomfort	Pain during dressing changes	often related to dressings adhering to the wound, or pain in the wound with exposure to air or the cleaning solutions
	Pain in between dressing changes	often related to the disease process, cancer pain, the wound location because of patient movement, or a reaction to the dressing
Odour malodorous smell	Necrotic tissue from tumour necrosis	typically a mild odour, may wash away
	Infection (Wound infections do not always have an odour)	odour may be a very strong anaerobes typically have a pungent, very strong odour that can fill the room pseudomonas may have a semi-sweet odour, and a blue-green hue in the wound
Exudate discharge, draining, oozing	Quantify amount of exudate	dry, scant, moderate, copious
	Qualify type of exudate	serous, serosanguineous, sanguineous, purulent
Bleeding vascular	Patient characteristics	friable tumour, coagulopathy
	Iatrogenic causes	adherent dressings, anticoagulant therapy
Edema swelling	Perhaps from decreased normal lymphatic drainage	typically distal to the location of the wound, for example, wounds in the upper chest & axilla – arm lymphoedema: groin wounds – leg lymphoedema, neck wounds: head lymphoedema

Table 4 8: Directed Assessment Will Assist in Deciding an Approach to Wound Management

Symptom	Cause of the Symptom	Description
Complications	Fistula formation	Often in the head & neck region, or the abdominal wall. Associated with drainage, and loss of function of the communicating organ.
	Incontinence	Urine or stool, often associated with a fistula.
	Infection	Cellulitis, may not have an odour
Functional Compromise from wound location	Restriction of movement	difficulty moving arms, legs or head & neck.
	Compromised daily activities	blindness, deafness, use of the mouth, eating, swallowing, shortness of breath.
Emotional Stress	Personal reaction to the tumour	Depression, discouragement, embarrassment, fear of being replaced by cancer or looking at the tumour, anxiety, frustration, altered self-image & body image, difficulty coping with visual tumour growth & managing the wound.
Social Concerns	Changes in interaction with others as a result of the wound	Social isolation from - patients withdraw and family, friends, and health care providers withdraw from the patient. Reactions of others to the patient (increased or decreased support) Dependency on others for care.
Patient's primary concern	Understand what bothers the patient most living with the wound	Frequently patients have a number of concerns and it is difficult to address them all at once.

Table 4 9: Evaluation Instructions for Content Validity of the Malignant Wound Assessment Tool #2 (MWAT.2) Provided to the Expert Judges

For every item (question), score 1, 2, 3, or 4 in the space provided.	1 = not relevant. 2 = somewhat relevant. 3 = relevant. 4 = very relevant.
There are three types of test items.	Verbal Analog Scale (VAS). Place score on the line in front of the item. Check ____ if the symptom applies. Place score on ____. Other ____. Place score on the ____.
Beside each score, state the dimension the item belongs to. (Example: Do you have difficulty Talking __ 3ps ____* Seeing __ 3ps ____ * Hearing __ 3ps ____*	d = demographic information. ps = physical symptom e = emotional concern s = social issue pe = physical examination
Provide an overall evaluation of the MWAT. Consider the following criteria.	Are the items clearly stated? Do you think the MWAT will be easy to administer? Do you think the MWAT will be a burden to the patient? Do the test items represent the patient's concerns?
Comments	Feel free to be critical.

* 3ps – indicates the test item was a relevant, physical symptom

Table 4 10: Patient and Interviewer Evaluation of the Malignant Wound Assessment Tool (MWAT)

Instructions to the Health Care Provider. Please read these questions to the patient or family member who answered the questions in the MWAT. These are open-ended questions. Please record the answer they give you.	Were the questions easy to understand? Did the questions I asked apply to your problem? Should I change any of the questions? Did I ask enough questions about the wound? Was it too difficult to answer these questions? Did I leave out anything that you would like to tell me about your wound?
Health Care Provider: please answer the following questions.	Were the questions clear? Was the MWAT easy to administer? Was it difficult for the patient to answer the questions (compared to a typical history and physical examination of the wound)? Other comments? What should be changed?

Table 5 1: MWAT.3 Results*

Item #	Explanation of Item	Response
2	Gender	Female = 7, Male = 3
3	Location of patient	cancer clinic= 4, hospital = 4, home = 2
5	Type of tumour	Breast = 5, head & neck = 2, other = 3
6	Age	Average age = 73.3
7	Duration of wound	Average = 11.1 months
17	Who provides care	Health care provider = 8
18	Number dressings	2/day = 3, 1/day = 3, 3/week = 2, 2/week = 1,NA=1
24a	Pain	8 / 10
25a	Itch	4 / 10
25b	Burn	5 / 10
25c	Sensitivity to touch	6 / 10
29	Swelling	7 / 10
32a	Anxious	7 / 10
32b	Discouraged	7 / 10
32c	Depressed	6 / 10
32d	Embarrassed	6 / 10
32e	Frustrated	8 / 10
32f	Isolated	3 / 10
33	Coping difficulty	8 / 10
44	Tumour presentation	Ulcerating = 7, fungating = 3, zosteriform = 1 subcutaneous spread = 2
56	Functional problem	9 / 10

* Note: N = 10

Table 5 2: Results of Text Items from MWAT.3 and MWAT.4

Item #	Item	Collective Responses
7	Item When did the patient first notice the wound?	Patients could remember the month they first noticed the wound, unless it was > 1 year.
7	How much does it change each month?	MWAT.4 – Missing data on 4/5 patients. MWAT.3 – Recorded as an approximation in all patients. One patient had a decrease in the wound size.
18	Name all dressings used	12/15 were using good quality dressings.
42	What are your daily activities?	Pattern emerged, similar to activity scales, e.g., Karnofsky Performance Scale (Yates, 1980).
43	Overall: What bothers you most about having the wound?	5/15 concerns with dressings. 4/15 just knowing the cancer is there. 3/15 associated functional problems. 3/15 associated symptoms.
47	What was the approximate size of the wound	Ranged from a 1 cm fistula from the base of the mouth through the neck, to covering 50% of the anterior chest wall.
48	Describe the wound bed	An entire range of results, fungating, ulcerating, subcutaneous spread, zosteriform, fistula, necrotic tissue, bleeding, ulcer, exudate.
58b 58c	What is the location of the fistula? What is the approx. fistula diameter?	Only 1/15 patients had a fistula.
41	Does the wound change your ability to do normal activities?	These two items yielded very similar results. 14/15 patients had difficulty functioning as a result of the wound location and associated symptoms.

Table 5 2: Results of Text Items from MWAT.3 and MWAT.4

Item #	Item	Collective Responses
	Does the patient have	wound location and associated symptoms.
59	difficulty functioning	
60	Document the appearance of the wound. 1 = Digital Imaging 2 = Photograph 3 = Tracing	All patients permitted photographs to be taken of the malignant wound. One patient requested that her photo never be published.

APPENDIX 2

KARNOFSKY PERFORMANCE STATUS SCALE

APPENDIX 2 - KARNOFSKY PERFORMANCE STATUS SCALE

Karnofsky Performance Status Scale.

Definition	%	Criteria
Able to carry on normal activity and to work; no special care needed.	100	Normal: no complaints; no evidence of disease.
	90	Able to carry on normal activity; minor signs or symptoms of disease.
	80	Normal activity with effort; some signs or symptoms of disease.
Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed.	70	Able to care for self; unable to carry on normal activity or to do active work.
	60	Requires occasional assistance, but is able to care for most of his needs.
	50	Requires considerable assistance and frequent medical care.
Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly.	40	Disabled; requires special care and assistance.
	30	Severely disabled; hospitalization is indicated; although death not imminent.
	20	Very sick; hospitalization necessary; active supportive treatment necessary.
	10	Moribund; fatal processes progressing rapidly.
	0	Dead.

Yates et al., (1980)

APPENDIX 3

PRELIMINARY RESEARCH SURVEY

APPENDIX 3 - PRELIMINARY RESEARCH SURVEY

Caring for Patients with Malignant Wounds

If you have been directly involved in caring for a patient with a malignant wound, please take 3 minutes to complete the following requests:

Describe the patients' history and physical examination to your partner (group).

List the symptoms that your patient experienced as a result of the wound. Do not identify your patient.

You may be asked to **report** the list of symptoms to the workshop attendees.

Please leave this list of symptoms with Dr. Valerie Schulz.

V. Schulz MD September 1999

APPENDIX 4

MALIGNANT WOUND ASSESSMENT TOOL (MWAT.1)

APPENDIX 4 - MALIGNANT WOUND ASSESSMENT TOOL (MWAT.1)

Patient Information: This information may be obtained from the chart or the patient

Date		
Date of birth		
Tumour diagnosis		
Other medical problems		
Cancer treatment	Radiation therapy - location & dose	Chemotherapy
Previous		
Current		
Medication		
Allergies		

_____

Signature

MALIGNANT WOUND SURVEY

Patient Survey: This information is obtained by interviewing the patient. Only patient opinions are recorded in this section. Record the patient's responses not your interpretation of the response. You may explain the terms and questions to the patient if required.

PHYSICAL SYMPTOMS

PAIN	Severity No pain 0 — Worst pain 10	
	- Discomfort	Yes_____ No_____
	- Irritation	Yes_____ No_____
	- Pressure	Yes_____ No_____
	- Tightness	Yes_____ No_____
	- Burning	Yes_____ No_____
	- Stabbing	Yes_____ No_____
	- Heat sensitive	Yes_____ No_____
	- Sensation of crawling	Yes_____ No_____
	- Sensitive to light touch	Yes_____ No_____
	- Itchy	Yes_____ No_____
	Other (if yes, explain)	

ODOUR		
	Patient perceived odour: If no, continue to next section.	
	Patient perceived odour: If yes, please complete the following questions.	
	- No odour at close range	Yes_____ No_____
	- Faint odour at close range	Yes_____ No_____
	- Moderate odour in the room	Yes_____ No_____
	- Strong odour in the room	Yes_____ No_____
	Odour bothersome to patient. Severity of odour: No odour Intolerable 0 10	
DISCHARGE (Weeping, drainage, oozing)	If no discharge present, continue to next section.	
	If discharge present, please complete the following questions.	
	Quantity	
	- Dry	Yes_____ No_____
	- Mild	Yes_____ No_____
	- Moderate	Yes_____ No_____
	- Excessive	Yes_____ No_____
	Quality	
	- Clear Yellow	Yes_____ No_____
	- Blood Tinged	Yes_____ No_____
	- Pus	Yes_____ No_____

BLEEDING	If no bleeding present, continue to next section.	
	If bleeding present, please complete the following questions.	
	Quantity	
	- None	Yes_____ No_____
	- Scant	Yes_____ No_____
	- Mild	Yes_____ No_____
	- Moderate	Yes_____ No_____
	- Heavy	Yes_____ No_____
	Causes	
	- Bleeding Disorder	Yes_____ No_____
	- Friable tumour	Yes_____ No_____
	- Anticoagulation therapy	Yes_____ No_____
	- Adherent Dressings	Yes_____ No_____
SWELLING (EDEMA)	If no swelling present, continue to next section.	
	If swelling present, please complete the following questions.	
	- Swelling associated with the wound	Yes_____ No_____
	- Tightness	Yes_____ No_____
	- Pressure	Yes_____ No_____
SKIN	Wound	
	- Heaviness	Yes_____ No_____
	- Dryness	Yes_____ No_____
	- Hardening	Yes_____ No_____
	Skin breakdown around the wound.	Yes_____ No_____
	- Radiation skin changes	Yes_____ No_____
	- Other	

FUNCTIONAL ISSUES	Difficulty moving	
	- Head and neck	Yes_____ No_____
	- Arms	Yes_____ No_____
	- Legs	Yes_____ No_____
	- Chest	Yes_____ No_____
	- Abdomen	Yes_____ No_____
	Difficulty in functioning of:	
	- Talking	Yes_____ No_____
	- Eating	Yes_____ No_____
	- Drinking	Yes_____ No_____
	- Swallowing	Yes_____ No_____
	- Speech compromised	Yes_____ No_____
	- Drooling	Yes_____ No_____
	- Blindness	Yes_____ No_____
	- Deafness	Yes_____ No_____
	- Other	Yes_____ No_____
	Incontinence	
	- Bladder	Yes_____ No_____
	- Vaginal	Yes_____ No_____
	- Rectal	Yes_____ No_____
	- Other	
	Fistula	
	- Abdomen	Yes_____ No_____
	- Perineum	Yes_____ No_____
	Infection	
	- Heat	Yes_____ No_____

	- Fever	Yes_____ No_____
	- Chills	Yes_____ No_____
	- Odour	Yes_____ No_____
	- Bleeding	Yes_____ No_____
	- Exudates	Yes_____ No_____
	- Redness	Yes_____ No_____
	Fatigue	
	- Mental	Yes_____ No_____
	- Physical	Yes_____ No_____

PSYCHOLOGICAL ISSUES

DEPRESSION	Depression	
	- Discouragement	Yes_____ No_____
	- Depression – disfigurement	Yes_____ No_____
	- grief	Yes_____ No_____
	Fear	
	- Dehiscence	Yes_____ No_____
	- Bleeding/bleeding to death	Yes_____ No_____
	- Total replacement of all by cancer	Yes_____ No_____
	- Visualization of the tumour	Yes_____ No_____
	- Visual fear	Yes_____ No_____
	- Anxiety	Yes_____ No_____
	- Self Image	Yes_____ No_____
	- Disfigurement	Yes_____ No_____
	- Loss of self image	Yes_____ No_____
	- Body image	Yes_____ No_____
	- Change in body image	Yes_____ No_____
	- Feeling ugly	Yes_____ No_____
	- Loss of self esteem	Yes_____ No_____
	- Denial	Yes_____ No_____
	- Embarrassment	Yes_____ No_____
	Psychological effects	
	- Reminder of growth	Yes_____ No_____
	- Unable to look at wound	Yes_____ No_____
	- Cosmetic distress	Yes_____ No_____
	- Visual distress	Yes_____ No_____

	- Emotional distress with visibility of wound	Yes_____ No_____
	- Worry about dressing wound	Yes_____ No_____
	- Frustration	Yes_____ No_____
	- Existential distress	Yes_____ No_____
	- Coping issues	Yes_____ No_____
	- Anger	Yes_____ No_____

SOCIAL ISSUES

ISOLATION	Family and Friends	
	- Withdrawal	Yes_____ No_____
	- Loneliness	Yes_____ No_____
	- Accepted in society	Yes_____ No_____
	- Dependence on others for care	Yes_____ No_____
	Environment	
	- Private room	Yes_____ No_____
	Sexuality	
	- Decreased sexuality	Yes_____ No_____
	- Decreased intimacy	Yes_____ No_____
	Effect on:	
	- Family	Yes_____ No_____
	- Visitors	Yes_____ No_____
	- Caregivers	Yes_____ No_____
	- Nurses	Yes_____ No_____
	Embarrassment	
	- Nurses	Yes_____ No_____
	- Personally	Yes_____ No_____
	- Offensive odour	Yes_____ No_____

NUTRITION

APPETITE	Decreased appetite due to odour	Yes_____ No_____
	Lack of appetite	Yes_____ No_____
	Hunger pangs	Yes_____ No_____
	Anorexia	Yes_____ No_____
	Nausea	Yes_____ No_____
	Cachexia	Yes_____ No_____

MALIGNANT WOUND SURVEY

Physical Examination: This information is obtained by observing the patient only. Patient opinions are not recorded in this section.

WOUND CLASSIFICATION	Fungating	Yes _____ No_____
	Ulcerating	Yes _____ No_____
	Subcutaneous spread	
	Zosteriform lesions (small, isolated tumors)	Yes _____ No_____
LOCATION	Head & Neck	Yes _____ No_____
	Chest	Yes _____ No_____
	Abdomen	Yes _____ No_____
	Back	Yes _____ No_____
	Upper Extremities	Yes _____ No_____
WOUND	Wound Bed	
	- % Necrotic tissue	_____%
	- % Eschar	_____%
	- % Granulating tissue	_____%
	Exudate	
	Quantity	
	- Dry	Yes _____ No_____
	- Mild	Yes _____ No_____
	- Moderate	Yes _____ No_____
	- Copious	Yes _____ No_____
	Quality	
	- Serous	Yes _____ No_____
	- Serosangious	Yes _____ No_____

	- Purlent	Yes _____ No_____
	Odour	
	- Patient perceived odour	Yes _____ No_____
	- No odour at close range	Yes _____ No_____
	- Faint odour at close range	Yes _____ No_____
	- Moderate odour in the room	Yes _____ No_____
	- Strong odour in the room	Yes _____ No_____
	Infection	
	- Redness	Yes _____ No_____
	- Heat	Yes _____ No_____
	- Tissue friability	Yes _____ No_____
	Bleeding	
	Quantity	
	- None	Yes _____ No_____
	- Scant	Yes _____ No_____
	- Mild	Yes _____ No_____
	- Moderate	Yes _____ No_____
	- Hemorrhage	Yes _____ No_____
	Causes	
	Patient characteristics	
	- Coagulopothy	Yes _____ No_____
	- Friable tumour	Yes _____ No_____
	Iatrogenic	
	- Anticoagulation therapy	Yes _____ No_____
	- Adherent Dressings	Yes _____ No_____

PERI-WOUND SKIN	Appearance	
	- Tracing (if applicable, <8"x11 ½)	Yes _____ No_____
	- Photographs	Yes _____ No_____

COMMENTS:

_____

_____

_____

_____

_____

_____

_____

_____

Signature

APPENDIX 5

MALIGNANT WOUND ASSESSMENT TOOL (MWAT.2)

APPENDIX 5 - MALIGNANT WOUND ASSESSMENT TOOL (MWAT.2)

This questionnaire is designed to provide a comprehensive, reproducible assessment for patients with malignant wounds. It is divided into 3 sections to reflect clinical practice.

Section 1 – Patient Demographics – It is the collection of demographic information to identify the individual, wound treatments and to understand the patient population.

Section 2 – Patient History – It is dedicated to understanding the patients perspective on living with a malignant wound. It includes questions on symptoms, emotional and social concerns.

Section 3 – Physical Examination – gIt is a systematic approach to examining the patients' wound. It is not a complete physical examination.

Patient Demographics - Section 1

Patient Information: This information may be obtained from the chart or the patient

Name	Female ____ Male____
Institution & Institutional Identification Number	
Date	
Date of birth	
Cancer diagnosis	
Approximate date the wound first appeared	
Current Wound Care Plan Cleaning regime - _____ _____ Dressings – type_____ Frequency of dressing changes_____ Who is providing the wound care? Family_____ health care provider_____ patient_____ other_____	

Cancer treatment	Previous (date)	Current
Radiation therapy - location & dose		
Chemotherapy		
Cancer Surgery		
Medication		
Allergies		

Patient History - Section 2

This information is obtained by interviewing the patient. Record the patient's (their care givers) responses not your interpretation of the response. You may explain the terms and questions to the patient if required.

This questionnaire is a guide to follow when patients and health care providers meet to discuss the patients' concerns about living with the wound.

1. Do you have any *pain* from the wound? **If no go to question 2**).

If Yes: a. How much *pain* do you have?

No pain Worst pain you can imagine

0 1 2 3 4 5 6 7 8 9 10

b. Does the *pain bother* you?

Not at all Always

0 1 2 3 4 5 6 7 8 9 10

(all responses that apply, slash all responses that do not apply)

c. When do you experience the pain?

____ during dressing changes ____ between dressing changes

____ with movement ____ at rest

d. What does the *pain in the wound* feel like?

____ pressure ____ tightness ____ burning ____ stabbing

____ heat sensitive ____ pins & needles ____ itchy ____ sensitive to light touch

____ other _____

e. Where is the *pain* located?_____

2. Do you notice any *smell* from the wound? **If no go to question 3).**

If Yes: a. How much does it *smell*?

No smell — Worst smell you can imagine

0 1 2 3 4 5 6 7 8 9 10

b. Does the *smell bother* you?

Not at all — Always

0 1 2 3 4 5 6 7 8 9 10

3. Do you *notice drainage* from the wound? No___. **If no go to question 4).**

If Yes: a. How much *drainage* do you have?

Not at all — Always draining a lot

0 1 2 3 4 5 6 7 8 9 10

b. Does the *drainage bother* you?

Not at all — Always

0 1 2 3 4 5 6 7 8 9 10

4. Do you *notice bleeding* from the wound? No___. **If no go to question 5).**

If Yes: a. How much *bleeding* do you have?

Not at all — Always bleeding a lot

0 1 2 3 4 5 6 7 8 9 10

b. Does the *bleeding bother* you?

Not at all — Always

0 1 2 3 4 5 6 7 8 9 10

5. Do you *notice swelling* (edema) because of the wound? No___. **If no go to question 6).**

If Yes: a. How much *swelling* do you have?

Not at all Extremely swollen

0 1 2 3 4 5 6 7 8 9 10

b. Does the *swelling bother* you?

Not at all Always

0 1 2 3 4 5 6 7 8 9 10

c. Where is the *swelling* located?

____ arms ____ legs ____ head & neck area

6. Is it difficult to do normal activities because of the wound? No___. **If no go to question 7).**

If Yes: a. What do you have difficulty doing? Please check the ones that apply to you.

____ use your arms ____ walk ____ talk ____ eat ____ drink

____ swallow ____ see ____ hear ____ breathe ____ prevent drooling

____ other _____

7. Does the wound affect your appetite?

Not at all Always

0 1 2 3 4 5 6 7 8 9 10

8. Has the *normal skin* around the wound changed? No___. **If no go to question 9).**

If Yes: a. Describe the change. _____

b. Does the *skin around the wound bother* you?

Not at all Constantly

0 1 2 3 4 5 6 7 8 9 10

c. What has damaged the skin?

____ dressing ____ tape ____ other _____

d. Should the dressing for your wound look good?

Not important Very important

0 1 2 3 4 5 6 7 8 9 10

e. Does the look of the dressing change the way you feel when visiting with others?

Not at all Always

0 1 2 3 4 5 6 7 8 9 10

f. Does living with your wound make you feel any of the following:

a. discouraged?

Not at all Always

0 1 2 3 4 5 6 7 8 9 10

b. depressed?

Not at all Always

0 1 2 3 4 5 6 7 8 9 10

9. Does the wound change the way you look at yourself in general (your self-image)?

Not at all Completely

0 1 2 3 4 5 6 7 8 9 10

10. Does the wound change the way you think about your body (your body-image)?

Not at all Completely

0 1 2 3 4 5 6 7 8 9 10

12. Does the wound change your self-esteem?

Not at all Completely

0 1 2 3 4 5 6 7 8 9 10

13. Does the wound make you feel embarrassed?

Not at all Extremely

0 1 2 3 4 5 6 7 8 9 10

14. Does the wound make you feel angry?

Not at all Extremely

0 1 2 3 4 5 6 7 8 9 10

15. Does the wound make you feel frustrated?

Not at all Extremely

0 1 2 3 4 5 6 7 8 9 10

16. Does the wound make you feel anxious?

Not at all Extremely

0 1 2 3 4 5 6 7 8 9 10

17. Are you afraid to look at the wound?

Not at all Extremely

0 1 2 3 4 5 6 7 8 9 10

18. Are you afraid when the wound changes?

Not at all Always

0 1 2 3 4 5 6 7 8 9 10

19. Do you have difficulty coping with the wound?

Not at all Always

0 1 2 3 4 5 6 7 8 9 10

20. Do family members treat you differently since you developed the wound?

Not at all Always

0 1 2 3 4 5 6 7 8 9 10

21. Do friends treat you differently since you developed the wound?

Not at all Always

0 1 2 3 4 5 6 7 8 9 10

22. Do you avoid being with people because of the wound?

Not at all Always

0 1 2 3 4 5 6 7 8 9 10

23. Do you feel people avoid you because of the wound?

Not at all Always

0 1 2 3 4 5 6 7 8 9 10

24. Does the wound make you feel isolated from other people?

Not at all Always

0 1 2 3 4 5 6 7 8 9 10

Overall:

_____

What bothers you most about having the wound?

_____

_____

Physical Examination - Section 3

Physical Examination: This information is obtained by observing the patient only. Patient opinions are not recorded in this section. The examiner performs the physical examination and records the findings.

Where is the wound located? Please check all that apply.

____ head & neck ____ chest ____ abdomen ____ back ____ axilla

____ genital region ____ buttock ____ upper extremity ____ lower extremity

Wound Classification

Please classify the wound:

Fungating (wound protruding off the body surface)_____

Ulcerating (wound creating an ulcer bed, often associated with fistulas)_____

Zosteriform lesions (small, isolated tumors, appearance similar to herpes zoster)_____

Subcutaneous Spread (flat, spreading wound, may not have open areas)_____

If yes – what type of subcutaneous spread is present?

Carcinoma erycypeloidies (erythema, appearance of cellulitis)_____

Carcinoma en cuirass (dry, flat indurated skin)_____

Elephantiasic skin changes (thick, raised induration skin)_____

Scerous skin changes (scleraderma tightness in appearnace)_____

What is the approximate wound size?_____

What is the pattern of wound spread?_____

What is the rate of wound growth? _____

Describe the wound bed. Provide short answers.

Necrotic tissue_____

Eschar (blackened necrotic tissue)_____

Granulating tissue_____

Wound bed colours_____

HEALTH CARE PROVIDER, please state if YOU detect odour, exudate, bleeding, or patient complications as a result of the wound. This is not the patients' opinion.

ODOUR

No odour Intolerable odour

0 1 2 3 4 5 6 7 8 9 10

What is the cause of the odour? Please check all that apply.

____ sloughing necrotic tissue ____ foul exudate ____ infection

____ fever ____ erythema

EXUDATE

No exudate (dry) Copious exudate

0 1 2 3 4 5 6 7 8 9 10

Quality of the exudate, please check all that apply.

____ serous ____ serosangious ____ purulent

BLEEDING

No bleeding Hemorrhage

0 1 2 3 4 5 6 7 8 9 10

Please check the cause of the bleeding. Please check all that apply.

____ patient characteristics: coagulopathy ____ friable tumour

____ iatrogenic causes: anticoagulation therapy ____ adherent dressings

Is the wound causing any COMPLICATIONS (i.e., fistulas, incontinence)?

Complications associated with the wound:

Fistula: No_____ Yes_____. If a fistula is present please fill in the following blanks:

Location: _____

Size: _____

Appearance of drainage: _____

Amount of drainage: _____

Difficulty moving as a result of the wound: No_____ Yes_____

If, yes, please answer the following:

____ arms ____ legs ____ head & neck _____ other

Does the patient experience functional compromise ? Please check all that apply.

Incontinence: ____ urine ____ stool

Changes in normal function: ____ speech ____ hearing

____ swallowing ____ vision

Other

_____

_____

Has the PERI-WOUND SKIN changed?

No skin changes Peri-wound skin is completely changed

0 1 2 3 4 5 6 7 8 9 10

Peri-wound skin: dry____ macerated____

Do the dressings damage the normal skin? Yes____ No____

Does tape damage the normal skin? Yes____ No____

Are radiation skin changes apparent? Yes____ No____

Are changes from surgery apparent? Yes____ No____

Other

***Tracing - Complete if digital imaging is not available and the wound is < 8.5" x 11".**

Place a piece of plastic wrap (from grocery store) over the wound, then place an acetate sheet (clear overhead projector sheet) over the plastic wrap. Trace the wound. Keep the acetate and discard the plastic wrap. When this is repeated at follow-up visits, you can compare the wound changes over time.

APPEARANCE OF THE WOUND	- *Tracing (applicable if digital imaging is not available and the wound is < 8.5" x 11")	Yes_____ No_____
	- Digital Imaging	Yes_____ No_____
	- Photograph	Yes_____ No_____
	- Number of photographs required	Yes_____ No_____
	- Location of photographs	Yes_____ No_____

COMMENTS:

Signature

APPENDIX 6

MALIGNANT WOUND ASSESSMENT TOOL (MWAT.3)

APPENDIX 6 - MALIGNANT WOUND ASSESSMENT TOOL (MWAT.3)

Malignant wounds are actually malignant, cancer growth within the skin. They care caused by either a primary tumor in the skin, or are secondary to internal malignancies such as breast cancer. They are not benign wounds in cancer patients. Malignant wounds differ from benign wounds. The desired primary outcome measures shift from wound healing in benign wounds, to impeccable symptom management in non-healing malignant wounds. The MWAT has been designed to be an assessment questionnaire for patients with malignant wounds.

The MWAT is 4 pages in length. It has been designed to longitudinally follow patients for 4 visits. Each question has been based on evidence that the problem in the question frequently exists in patients with malignant wounds. The last page of this document is a patient survey.

- The first page is the **Patient Demographics.** It identifies the patient, their type of cancer and the current management of their malignant wound.
- The second page is the ***Code Chart**. Use the chart to complete the following 2 pages.
- The third page is the **Patient History** assessment. There are some codes listed at the bottom of this page for answering the questions. The patient or their representative family members will provide the answers to the questions and the interviewer will read the questions and record their answers.
- The forth page is the **Physical Examination** page. The code sheet is required to answer these questions. The interviewer conducts this examination and records their findings.
- The fifth page is the **Patient Evaluation of the Malignant Wound Assessment Tool**. These questions are designed to provide an evaluation of the tool from the patients' perspective. These questions are intended to determine the clarity of the questions asked in the tool, the representation of the patient population, (ie. does the tool include the patient concerns), the relevance of the questions asked (ie. are the questions asked appropriate) and the patient burden in responding to the questionnaire. There is space provided for the interviewer to provide comments on this page as well.

Thank you for testing the MWAT. For research results please contact <dvschulz@sympatico.ca>

Valerie Schulz MD Palliative Medicine LRCC

Patient Demographics

Patient Information: This information may be obtained from the chart or the patient

Name	Female ____ Male____
Institution	Institutional Identification Number
Cancer diagnosis	Date of birth
Approximate date the patient first noticed the wound	
Previous Radiation location & dose	
Previous Chemotherapy	
Previous Cancer Surgery	
Other sites of metastasis	
Previous medical problems	
Allergies	

DATE				
Current Radiation Therapy location & dose				
Current Chemotherapy				
Who is doing the wound care?[1] (see bottom of this table)				
What is the frequency of dressing changes? #/day, or #/week				
How is the wound cleaned?[2]				
Name all dressings being used.				
How effective is the wound care?[3] Describe				
Medications				

[1] 1 = family, 2 = health care provider, 3 = patient, 4 = other (state who)

[2] 1 = shower, 2 = saline, 3 = water, 4 = cleaning products (name), 5 = other (please state)

[3] 1=not at all, 2=somewhat, 3= usually, 4=always

Patient History

1 = not at all, **2** = mild /sometimes, **3** = moderate / usually, **4** = severe / all the time,

5 = does not apply

DATE				
Do you have pain: from the wound?				
during dressing changes?				
between dressing changes?				
Does your wound: Itch?				
Burn?				
Is your wound sensitive to light touch?				
Do you notice a smell from the wound?				
Do you have drainage from the wound?				
Does your wound bleed?				
Does the wound cause swelling?				
Does the wound change your appetite?				
Has the skin around your wound changed?				
Does your wound make you feel: anxious?				
discouraged?				
depressed?				
embarrassed?				
frustrated?				
isolated from other people?				
Is it difficult to cope with the wound?				
Does the wound change the way you look at: yourself in general (your self-image)?				
your body (body image)?				
Are you afraid to look at the wound?				
Does the look of the dressing change the way you feel when visiting with others?				
Are your family members supportive?				
Are your friends supportive?				
Do you have difficulty doing normal daily activities because of the wound?				
What difficulties? *see code 11				
What are your daily activities?				
Overall: What bothers you most about having the wound?				

*Code Charts

1 Location	2 Wound Classification	3 Skin Around Wound
1 = Head 2 = Neck 3 = Chest 4 = Abdomen 5 = Back 6 = Axilla 7 = Genital Region 8 = Buttock 9 = Upper extremity 10=Lower extremity	1 = Fungating (wound protruding off the body surface) 2 = Ulcerating (wound creating an ulcer bed, +/- with a fistulas) 3 = Zosteriform lesions (appearance similar to herpes zoster) 4 = Subcutaneous Spread flat, spreading wound, +/- open areas) If yes – what type of subcutaneous spread is present? 4a =Carcinoma erysipeloides (erythema,appearance of cellulitis) 4b = Carcinoma en cuirasse (dry, flat indurated skin) 4c = Elephantiasic skin changes (thick, raised induration skin) 4d = schirrhous dermal reaction (scleraderma like tightness) 5 = other, describe the wound	1 = Dry 2 = Wet 3 = Other_____ 4 = Normal **4 Causes of Damage** 1 = Moisture 2 = Dressings 3 = Tape 4 = Radiation 5 = Other_____

5 Odour	7 Exudate - drainage	9 Bleeding	11 Functional difficulty codes
1 = no odour 2 = odour near patient 3 = mild room odour 4 = strong room odour 5 = does not apply	1 = no exudate 2 = moist wound 3 = very moist, draining wound 4 = copious exudate 5 = does not apply	1 = no bleeding 2 = small amount of bleeding 3 = moderate bleeding 4 = severe bleeding 5 = does not apply	1 = Speech 2 = Hearing 3 = Swallowing 4 = Vision 5 = Difficulty moving arms 6 = Difficulty moving legs 7 = Difficulty moving head & neck 8 = Other a_____ 8b_____ 8c_____ 8d_____ 9 = No difficulty functioning
6 Cause of Odour	**8 Exudate Appearance**	**10 Cause of Bleeding**	
1 = necrotic tissue 2 = infection 3 = does not apply	1 = serous 2 = serosanginous 3 = purulent 4 = fistula exudate 5 = does not apply	1 = adherent dressings 2 = anticoagulation 3 = friable tumour 4 = tumour location (vessels) 5 = coagulopathy 6 = does not apply	

12 *Tracing - Complete if digital imaging is not available and the wound is < 8.5" x 11".

Place a piece of plastic wrap (from grocery store) over the wound, then place an acetate sheet (clear overhead projector sheet) over the plastic wrap. Trace the wound. Keep the acetate and discard the plastic wrap. When this is repeated at follow-up visits, you can compare the wound changes over time.

Physical Examination

* = see code chart

DATE				
Where is the wound located? * 1				
What is the wound classification? * 2				
What is the approximate size of the body surface affected by the wound?				
Approximately, how long does it take for the wound to double in size? (growth rate)				
Describe the wound bed, and include: 1 = necrotic tissue 2 = eschar (blackened necrotic tissue) 3 = granulating tissue Indicate the colours in the wound bed				
Describe the wound edges. 1 = flat, 2 = tunneling, 3 = elevated				
How severe is the wound odour? * 5				
What is the cause of the odour? * 6				
How much wound exudate is present? * 7				
What does the exudate look like? * 8				
How much does the wound bleed? * 9				
What is the cause of the bleeding? * 10				
What is the skin around the wound like?* 3				
IF: 1,2 or 3 What is causing the damage to the skin around the wound? * 4				
Does the patient have difficulty functioning? * 11 and describe				
Does the wound cause incontinence? 1 = urine, 2 = stool, 3 = no incontinence				
Is a fistula present? Y = yes, N = No				
If Yes: What is the location * 1?				
What is the approximate fistula diameter?				
Document the appearance of the wound. 1 = Digital Imaging, 2 = Photograph 3 = Tracing* (see code 12)				

Patient Evaluation of the Malignant Wound Assessment Tool

Please read these questions to the patient/family member who answered the questions in the MWAT. These are open-ended questions. Please record the answer they give you.

Were the questions easy to understand?

Did the questions I asked apply to your problem?

Did I ask enough questions about the wound?

Was it too difficult to answer these questions?

Did I leave out anything that you would like to tell me about your wound?

Health Care Provider – Please answer the following questions.

Were the questions clear?

Was the MWAT easy to administer?

Was it difficult for the patients to answer the questions – compared to a typical history and physical examination of the wound?

Other Comments

APPENDIX 7

MALIGNANT WOUND ASSESSMENT TOOL (MWAT.4)

APPENDIX 7 - MALIGNANT WOUND ASSESSMENT TOOL (MWAT.4)

Malignant wounds are the spread of cancer within the skin. They care caused by either a primary tumor in the skin, or are secondary to internal malignancies that spread to skin. They are not benign wounds in cancer patients. The desired primary outcome measures shift from wound healing in benign wounds, to impeccable symptom management in non-healing malignant wounds. The MWAT has been designed to be an assessment questionnaire for patients with malignant wounds.

The **MWAT** is 4 pages in length. It has been designed to longitudinally follow patients for 3 visits. Each question has been based on evidence that the problem in the question frequently exists in patients with malignant wounds. The last page of this document is a patient survey.

1. The first page is the **Patient Demographics.** It identifies the patient, their type of cancer and the current management of their malignant wound.
2. The second page is the **Patient History** assessment. There are some codes listed at the bottom of this page for answering the questions. The patient or their representative family members will provide the answers to the questions and the interviewer will read the questions and record their answers.
3. The third page is the ***Code Chart**. Use the chart to complete the following page and one question on the patient history assessment..
4. The forth page is the **Physical Examination** page. The code sheet is required to answer these questions. The interviewer conducts this examination and records their findings.
5. The fifth page is the **Patient Evaluation of the Malignant Wound Assessment Tool**. These questions are designed to provide an evaluation of the tool from the patients' perspective. These questions are intended to determine the clarity of the questions asked in the tool, the representation of the patient population, (ie. does the tool include the patient concerns), the relevance of the questions asked (ie. are the questions asked appropriate) and the patient burden in responding to the questionnaire. There is space provided for the interviewer to provide comments on this page as well.

Thank you for testing the MWAT. For research results please contact <dvschulz@sympatico.ca>

Valerie Schulz MD Palliative Medicine LRCC

Patient Demographics

Patient Information: This information may be obtained from the chart or the patient

Name		Female ____ Male____	
Institution		Institution Number	
Cancer diagnosis & date of diagnosis		Date of birth	
When did the patient first notice the wound? How much does it change each month			
Previous radiation, chemotherapy, cancer surgery			
Other sites of metastasis			
Previous medical problems			
Allergies			
DATE			
Current Radiation Therapy location & dose			
Current Chemotherapy			
Wound care is provided by: 1 = family, 2 = health care provider, 3 = patient, 4 = other			
What is the frequency of dressing changes? #/day, or #/week			
How is the wound cleaned? 1 = shower, 2 = saline, 3 = water, 4 = cleaning products, 5 = other			
Name all dressings being used.			
Describe wound care effectiveness 1 = not at all, 2 = somewhat, 3 = usually, 4 = always			
Medications			

Patient History

Please indicate how important the following concerns are:

FROM 0 = not at all - TO - 10 = overwhelming

In follow-up: You may tell the patient their previous response.

* = refer to the code chart on next page

DATE			
Do you have pain: from the wound?			
during dressing changes?			
between dressing changes?			
Does your wound: Itch?			
Burn?			
Is your wound sensitive to light touch?			
Do you notice a smell from the wound?			
Do you have drainage from the wound?			
Does your wound bleed?			
Does the wound cause swelling?			
Does the wound change your appetite?			
Does your wound make you feel: anxious?			
depressed?			
embarrassed?			
frustrated?			
isolated from other people?			
Is it difficult to cope with the wound?			
Are you afraid to look at the wound?			
Does the wound change the way you look at:			
yourself in general (your self-image)?			
your body (body image)?			
Is the look of the dressing important?			
Are your family members supportive?			
Are your friends supportive?			
Has the skin around your wound changed? 0-10 Describe			
Does the wound change your ability to do normal activities? 0-10 Describe *11			
What are your daily activities?			
Overall: What bothers you most about having the wound?			

*Code Charts

1 Location	2 Wound Classification
1 = Head 2 = Neck 3 = Chest 4 = Abdomen 5 = Back 6 = Axilla 7 = Genital Region 8 = Buttock 9 = Upper extremity 10=Lower extremity 11 = other_____	1 = Fungating (wound protruding off the body surface) 2 = Ulcerating (wound creating an ulcer bed, +/- with a fistulas) 3 = Zosteriform lesions (appearance similar to herpes zoster) 4 = Subcutaneous Spread flat, spreading wound, +/- open areas). If yes – what type of subcutaneous spread is present? 4a = Carcinoma erysipeloides (erythema,appearance of cellulitis) 4b = Carcinoma en cuirasse (dry, flat indurated skin) 4c = Elephantiasic skin changes (thick, raised induration skin) 4d = scirrhous dermal reaction (scleraderma like tightness) 5 = other, describe the wound

3 Odour	4 Cause of Odour	5 Exudate - drainage	6 Exudate Appearance
1 = no odour 2 = odour near patient 3 = mild room odour 4 = strong room odour 5 = does not apply	1 = necrotic tissue 2 = infection 3 = does not apply	1 = no exudate 2 = moist wound 3 = very moist, draining wound 4 = copious exudate 5 = does not apply	1 = serous 2 = serosanginous 3 = purulent 4 = fistula exudate 5 = does not apply 6 = _____
7 Bleeding	**8 Cause of Bleeding**	**9 Skin Around Wound**	**10 Causes of Damage**
1 = no bleeding 2 = small amount of bleeding 3 = moderate bleeding 4 = severe bleeding 5 = does not apply	1 = adherent dressings 2 = anticoagulation 3 = friable tumour 4 = tumour location (vessels) 5 = coagulopathy 6 = does not apply 7 = _____	1 = Normal 2 = Dry 3 = Wet 4 =Other_____	1 = Moisture 2 = Dressings 3 = Tape 4 = Radiation 5= Other_____

11 Functional difficulty codes	
1 = Speech	7 = Difficulty moving head & neck
2 = Hearing	8 = Other a _____
3 = Swallowing	8b._____
4 = Vision	8c._____
5 = Difficulty moving arms	8d._____
6 = Difficulty moving legs	9 = No difficulty functioning

12 *Tracing - Complete if digital imaging is not available and the wound is < 8.5" x 11".

Place a piece of plastic wrap (from grocery store) over the wound, then place an acetate sheet (clear overhead projector sheet) over the plastic wrap. Trace the wound. Keep the acetate and discard the plastic wrap. When this is repeated at follow-up visits, you can compare the wound changes over time.

Physical Examination

* = see code chart

DATE			
Where is the wound located? * 1			
What is the wound classification? * 2			
What is the approximate size of the wound? Measure length x width if possible.			
Describe the wound bed, and include: 1 =fibrous – necrotic tissue 2 = eschar (blackened necrotic tissue) 3 = granulating tissue Indicate the colours in the wound bed			
Describe the wound edges and state: 1 = flat, 2 = tunneling, 3 = elevated			
How severe is the wound odour? * 3			
What is the cause of the odour? * 4			
How much wound exudate is present? * 5			
What does the exudate look like? * 6			
How much does the wound bleed? * 7			
What is the cause of the bleeding? * 8			
What is the skin around the wound like?* 9			
Describe why? * 10			
Does the wound cause incontinence? 1 = urine, 2 = stool, 3 = no incontinence			
Is a fistula present? Y = Yes, N = No			
If Yes: What is the location * 1?			
What is the approximate fistula diameter?			
Does the patient have difficulty functioning? * 11 Describe			
Document the appearance of the wound. 1 = Digital Imaging, 2 = Photograph 3 = Tracing* (see code 12)			

Patient Evaluation of the Malignant Wound Assessment Tool

Please read these questions to the patient/family member who answered the questions in the MWAT. These are open-ended questions. Please record the answer they give you.

1. Were the questions easy to understand?

2. Did the questions I asked apply to your problem?

3. Should I change any of the questions? – go through the questions with the patient

4. Did I ask enough questions about the wound?

5. Was it too difficult to answer these questions?

6. Did I leave out anything that you would like to tell me about your wound?

Health Care Provider – Please answer the following questions.

Were the questions clear?

Was the MWAT easy to administer?

Was it difficult for the patients to answer the questions – compared to a typical history and physical examination of the wound?

Other Comments - What should be changed?

APPENDIX 8

MALIGNANT WOUND ASSESSMENT TOOL (MWAT.5)

APPENDIX 8 - MALIGNANT WOUND ASSESSMENT TOOL (MWAT.5)

Renamed: SCHULZ MALIGNANT WOUND ASSESSMENT TOOL

Malignant wounds are the spread of cancer within the skin caused by either a primary tumor in the skin, or are secondary to internal malignancies that spread to skin. They are not benign wounds in cancer patients. The desired primary outcome measures shift from wound healing in benign wounds, to impeccable symptom management in non-healing malignant wounds. The MWAT was designed to be an assessment questionnaire for patients with malignant wounds.

The MWAT is two pages in length. Each question was based on evidence that the problem in the question frequently exists in patients with malignant wounds. The last page is an MWAT evaluation.

1. The interviewer will; (a) read, (b) record answers and (c) answer items relating to signs.
2. Page one is the Patient Demographics. It identifies the patient, their type of cancer and the current management of their malignant wound.
3. Page two is a table evaluating; (a) patient history and (b) physical examination.
    a. The signs and symptoms are listed in the left hand column, each with a row outlining a range of options. Code one or more responses in each symptom row.
    b. Each row requires at least one response to complete the MWAT.
    c. Complete blanks with a check, number or word.
    d. The patient or family will respond to the symptom presence, intensity or both.
    e. Obtain the patients' rating (0 – 10), of symptom intensity were applicable.
    f. For a, b, c. options, record the letter(s) that best fit.
    g. The last 2 columns allow the MWAT to be tailored to the unique patient.
        i. Record other sign or symptom presentations – i.e., Frustration.
        ii. If applicable, record its intensity (0–10), e.g., Anxiety 8.
        iii. Record – na – if the question is not applicable (e.g.,. na, to odour).
4. The third page is the Patient and Interviewer Evaluation of the Malignant Wound Assessment Tool. This is intended to determine; (a) the clarity of MWAT questions, (b) patient population representation, (ie. does the tool include the patient concerns), (c) the relevance of the questions asked (ie. are the questions asked appropriate) and (c) the patient burden in responding to the questionnaire.

Thank you for testing the MWAT. For study results please contact dvschulz@sympatico.ca

Valerie Schulz MD Palliative Medicine LHSC

Schulz Malignant Wound Assessment Tool

Patient Information: This information may be obtained from the chart or the patient

Name			Female ____ Male____
Date			Date of birth
Institution/location			Institution Number
Cancer diagnosis			Date of diagnosis
Previous	Radiation		
	Chemotherapy		
	Cancer surgery		
Current	Radiation		
	Chemotherapy		
	Cancer surgery		
Other metastases			
Date patient first noticed the wound			
Rate wound changes / month / year			
Wound care is provided by: 1 = family, 2 = health care, 3 = patient, 4 = other			Karnofsky performance status 0 – 100
Method of cleaning wound: 1 = saline, 2 = water, 3= cleaning products, 4 = other			Dressing changes #/day or #/week
Name all dressings and wound treatments			
Is the appearance of the wound covering important? (dressing / clothing)			
Describe wound care effectiveness.			
State previous wound care attempted			
Relevant Medical Problems			
Allergies			
Medications			

Patient and Interviewer Evaluation of the Malignant Wound Assessment Tool

Please read these questions to the patient/family member who answered the questions in the MWAT. These are open-ended questions. Please record the answer they give you.

1. Were the questions easy to understand?

2. Did the questions apply to your problem?

3. Should any questions be changed?

4. Were enough questions asked about the wound?

5. Was it too difficult to answer these questions?

6. Is there anything else you would like to tell me about your wound?

Health Care Provider – Please answer the following questions.

Were the questions clear?

Was the MWAT easy to administer?

Was it difficult for the patients to answer the questions – compared to a typical history and physical examination of the wound?

Other Comments - What should be changed?

Schulz Malignant Wound Assessment Tool (SMWAT) Items relate to malignant wound concerns																				
Patient's Name					Date								Interviewer							
Answer 1 or more items per row					0 = not at all to 10 = overwhelming								Circle 'na' if row not applicable							
1. Pain	During dressing changes 0 – 10				Between dressing changes 0 - 10				Burning 0 - 10				Sensitive to light touch 0 - 10				Itching 0 - 10			
2. Patient Describes	Smell 0 – 10				Drainage 0 - 10				Bleeding 0 - 10				Swelling 0 - 10							
3. Social issues	Family support 0 – 10				Friends support 0 - 10				Health care support 0 - 10				Social isolation 0 - 10							
4. Emotional concerns Does the patient feel:	Anxious 0 –10				Depressed 0 – 10				Embarrassed 0 -10				Fear 0 - 10							
5. What bothers the patient most?																				
6. Wound Classification	Fungating				Ulcerating				Subcutaneous a.Dry / b.Raised				Multiple nodules							
7. Wound bed	% Pink / red wound				% necrotic tissue covering				Describe											
8. Wound edges	Flat				Elevated wound				Elevated edge				Tunneling							
9. Odour -describe	na	Under dressing			Near patient				Moderate odour				Strong odour							
10. Odour - cause	na	Necrotic tissue			Infection				Exudate											
11. Exudate amount	na	Dry			Moist				Wet				Copious							
12.Exudate describe	na	Serous			Purulent				Fistula exudate				Brown							
13. Bleeding amount	na	Minimal			Moderate				Severe				Intermittent							
14. Bleeding - cause	na	Dressing			Coagulation				Friable tumour				Blood vessels							
15. Describe wound include location																				
16. Measurement	Tracing		Photograph				Measurements (cms)													
17. Peri-wound skin	na	Treatment effects		Dry		Moist		Discoloured												
18. Function altered R = right L=left	na	Circle all that apply: Eye – R / L Ear – R / L Breathing Mouth Opening Chewing Swallowing Shoulder – R / L Arm, hand – R /L Leg, Foot – R / L Bowel Bladder																		
19. Edema in or distal to wound	na	Circle edema location(s): (a) in wound around wound distal to wound (b) arm R / L leg R / L Head Neck																		